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Boyle et al.

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(54) **RAMP-SHAPED INTERVERTEBRAL IMPLANT**

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(22) Filed: **Jun. 8, 1999**

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(52) **U.S. Cl.** **623/17.16**; 623/17.11; 623/16.11
(58) **Field of Search** 623/16.11, 23.51, 623/23.61, 17.11, 17.16; 606/60, 61

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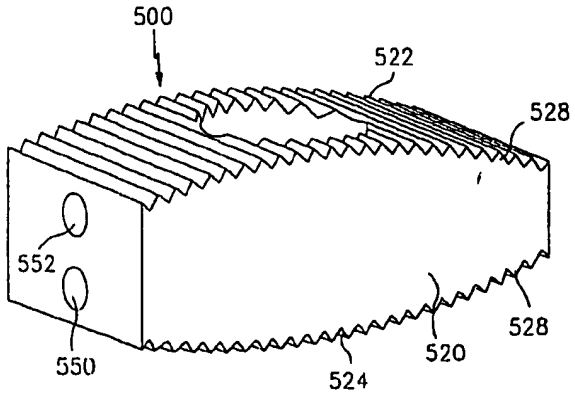
(74) *Attorney, Agent, or Firm*—Dilworth & Barrese, LLP

(57) **ABSTRACT**

A ramp-shaped intervertebral implant is disclosed. The implant has a body having a first end, a second end, a top surface and a bottom surface. At least one of the top and bottom surfaces is tapered and converges towards the second end of the body. An opening extends through the body and has one end opening onto the top surface of the implant and the other end opening onto the bottom surface of the implant. The implant can be formed from the diaphysis or metaphysis of a long bone, wherein the intramedullary canal of the long bone defines the opening. Alternately, the implant can be made from any biocompatible material having the requisite strength requirement.

19 Claims, 6 Drawing Sheets



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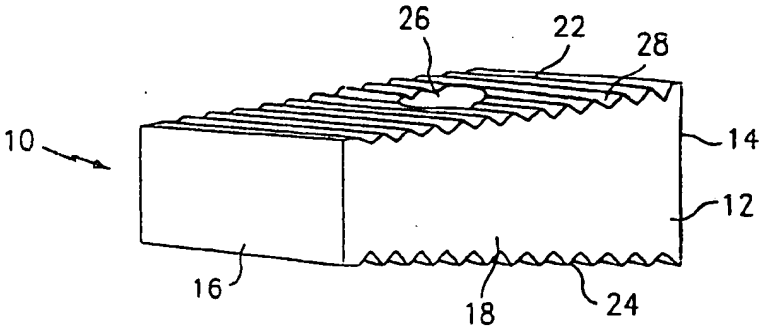

FIG. 1

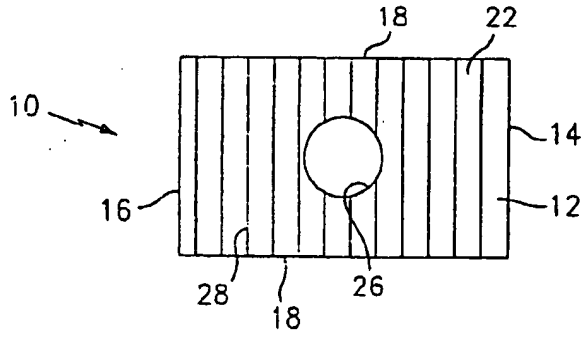

FIG. 2

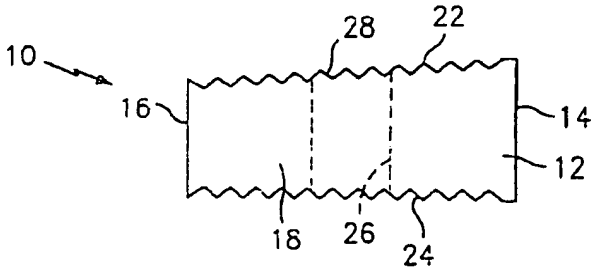

FIG. 3

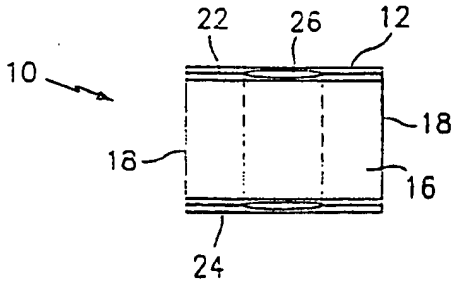

FIG. 4

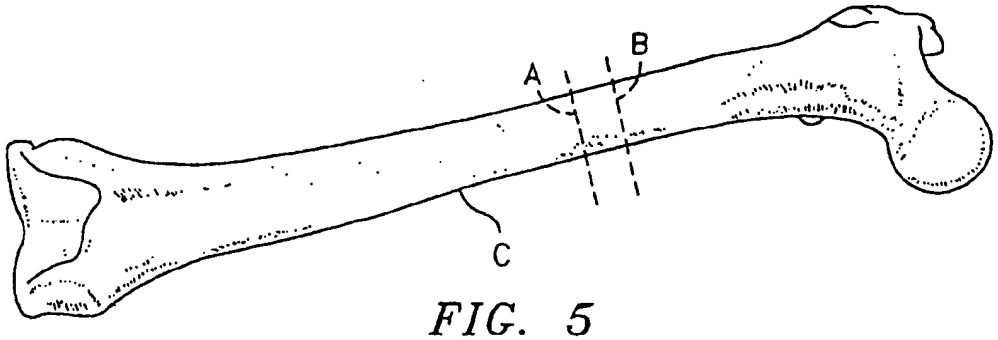

FIG. 5

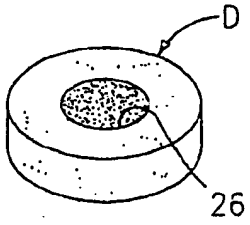

FIG. 6

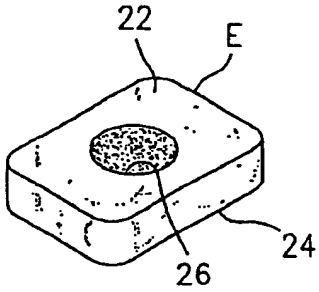

FIG. 7

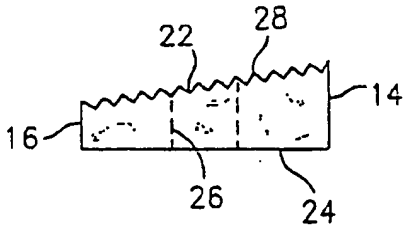

FIG. 8

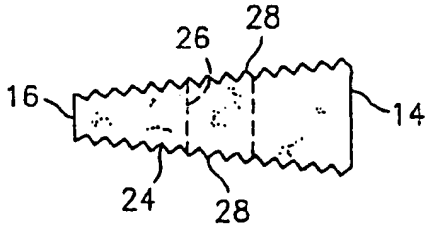

FIG. 9

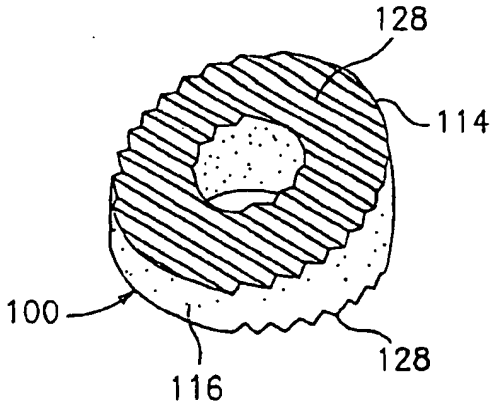

FIG. 10

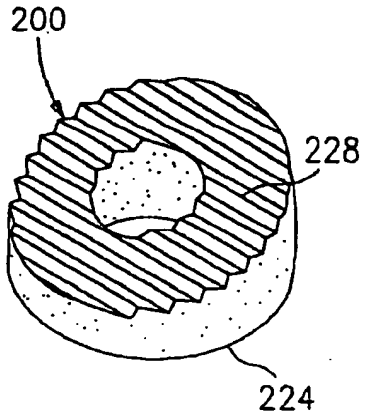

FIG. 11

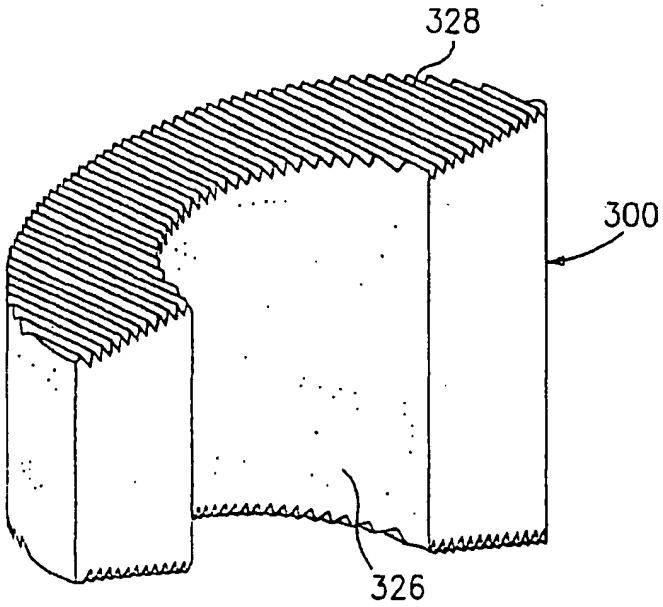

FIG. 12

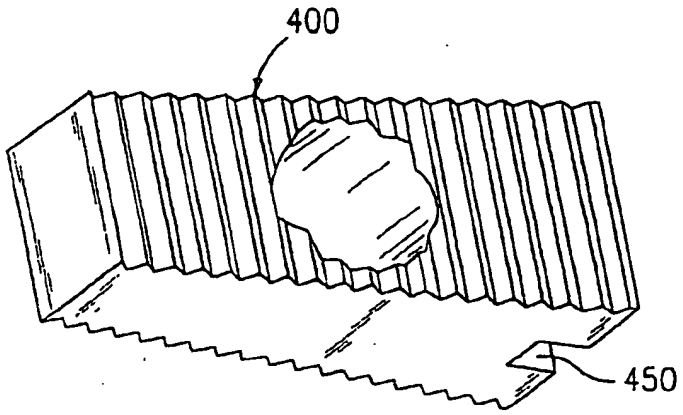

FIG. 13

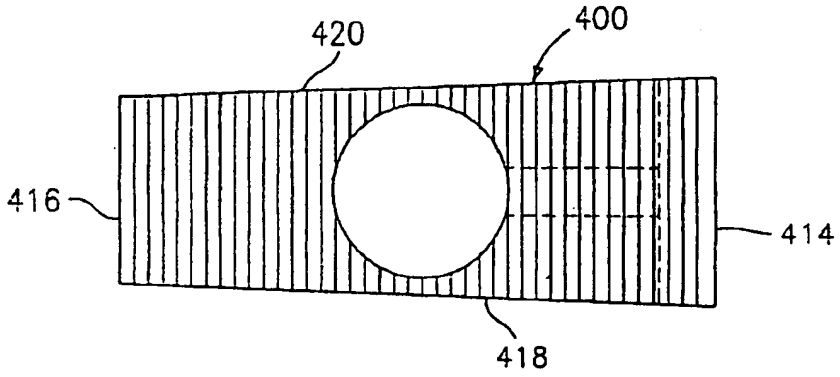

FIG. 14

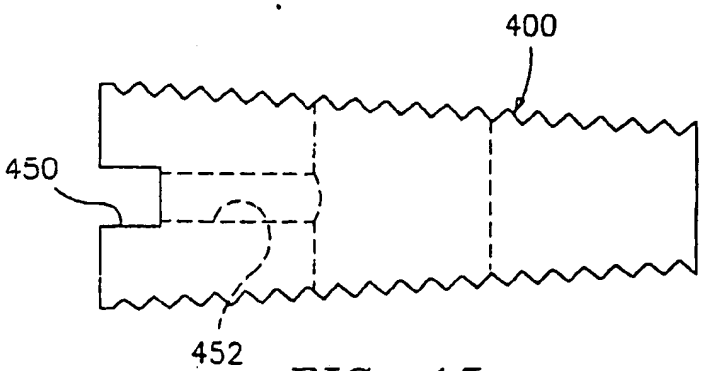

FIG. 15

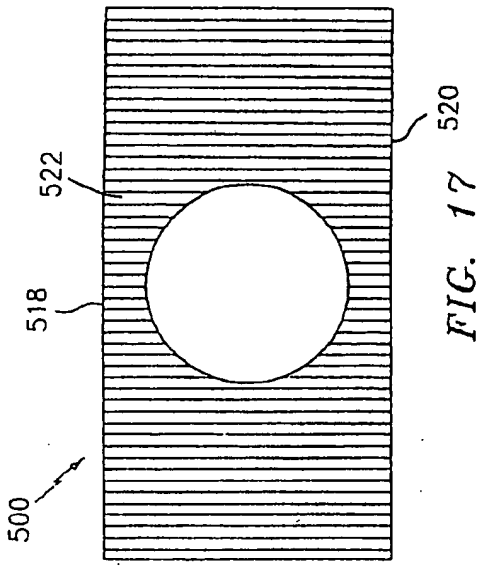

FIG. 17

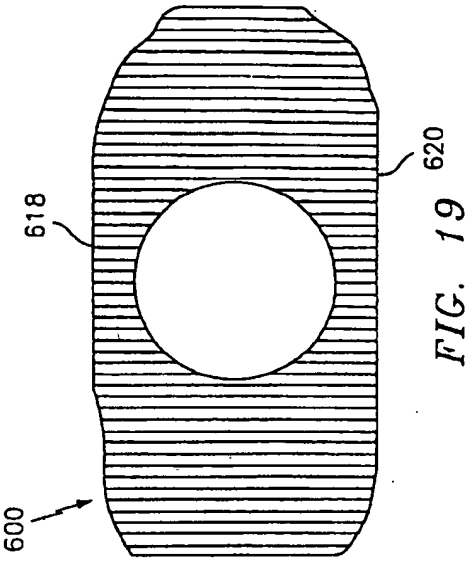

FIG. 19

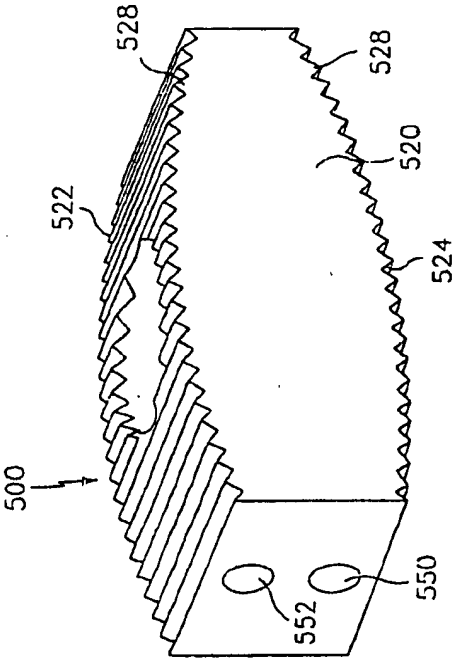

FIG. 16

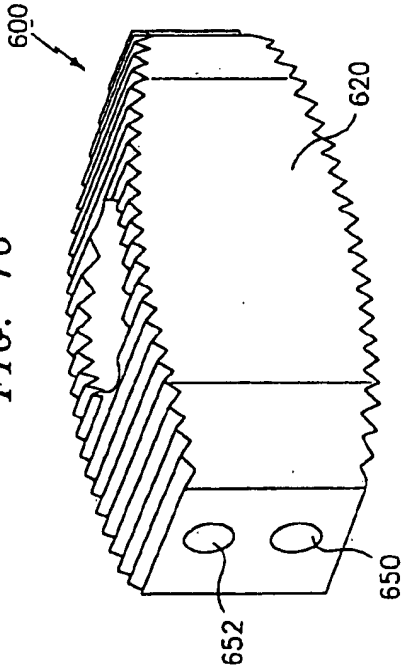

FIG. 18

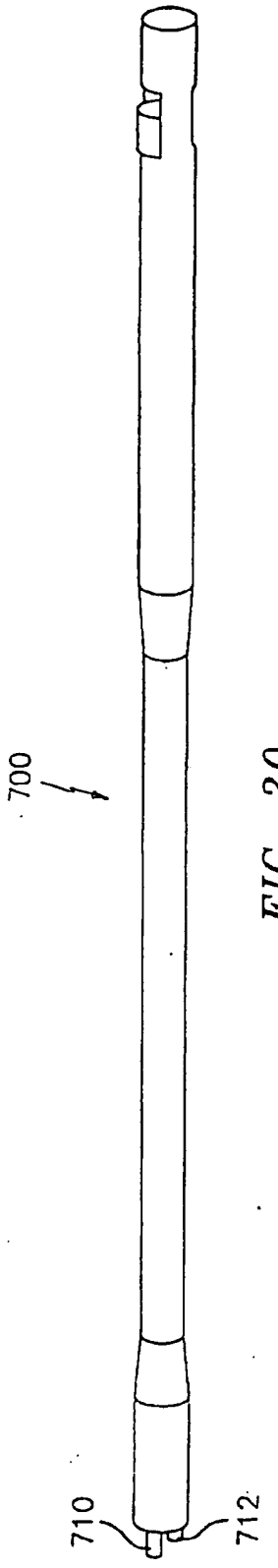

FIG. 20

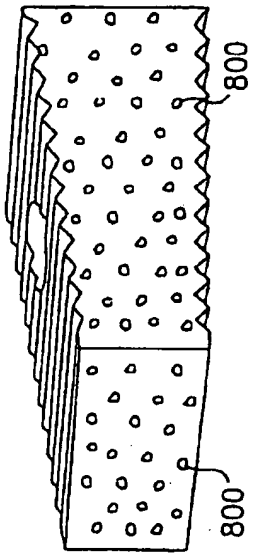

FIG. 21

RAMP-SHAPED INTERVERTEBRAL IMPLANT

BACKGROUND OF THE INVENTION

1. Technical Field

The present disclosure relates generally to intervertebral implants for spinal fusion and, more particularly, to a ramp-shaped intervertebral implant having a top surface and a bottom surface and at least one opening extending between the top and bottom surfaces.

2. Background of Related Art

Surgical procedures for fusing adjacent vertebrae together to treat back pain in patients with ruptured or degenerated intervertebral discs, spondylolisthesis or other pathologies are well known. Typically during such a procedure, a spinal implant is placed into the intervertebral space in a position to engage adjoining vertebrae. The implant is constructed from a biocompatible material which is adapted to fuse with the adjacent vertebrae to maintain proper spacing and lordosis between the adjacent vertebrae, i.e., maintain the disc space.

A variety of different types of intervertebral implants have been developed to perform this function including spinal fusion cages, threaded bone dowels and stepped bone dowels. Exemplary implants are disclosed in U.S. Patent Applications filed on even date herewith, under Certificate of Express Mail Label Nos. EL260888080US and EL071686220US, and entitled "Intervertebral Implant" and "Keyed Intervertebral Dowel", respectively, the entire disclosures of which are incorporated herein by reference.

One type of intervertebral implant has a wedge configuration. U.S. Pat. No. 5,425,772 to Brantigan discloses a wedge-shaped implant having an anterior end, a posterior end, front and rear walls, top and bottom walls and sidewalls. The implant is constructed from biocompatible carbon reinforced polymer or alternately of traditional orthopedic implant materials such as chrome cobalt, stainless steel or titanium. The top and bottom walls are tapered from the anterior end of the implant to the posterior end such that the anterior end of the implant has a height greater than the height of the posterior end of the implant. The top and bottom of the implant are continuous and unslotted and include a series of transverse teeth or serrations extending thereacross. A slot configured to receive bone graft material extends through the implant between the sidewalls.

During insertion of Brantigan's implant into the intervertebral space, the adjoining vertebrae are tensioned and a portion of disc tissue between the vertebrae is cut and removed to form channels between the vertebrae. The implant is positioned in the channel such that the teeth formed on the top and bottom surfaces of the implant engage the adjoining vertebrae. During a surgical spinal fusion procedure, two of Brantigan's implants are inserted between the adjoining vertebrae to be fused.

U.S. Pat. No. 5,443,514 to Steffee also discloses a wedge-shaped implant having upper and lower toothed surfaces, a pair of parallel side surfaces, a pair of end surfaces and a plurality of openings extending between the side surfaces. The implant is constructed from an injection molded chopped carbon fiber reinforced polymer. The openings facilitate blood flow and bone growth from one side of the implant to the other. Steffee's implant is adapted to receive an insertion tool which during insertion of the implant between adjoining vertebrae rotates the implant from a horizontal to a vertical orientation. During a surgical procedure, two of Steffee's implants are positioned between adjoining vertebrae.

Conventional wedge-shaped intervertebral implants, including those described above, have several drawbacks. For example, although autograft wedges are known, e.g., iliac crest wedges, typically, conventional wedge-shaped implants are constructed from materials which do not remodel but rather remain in place forever or until removal is necessitated, i.e., at least some or all of the implant is not replaced by new bone, but rather the implant itself is incorporated into the body. Since the implants usually become adherent to the adjoining vertebrae, if removal of the implant is ever necessitated, the procedure to effect removal is complicated and dangerous to the patient. Moreover, in conventional wedge-shaped implants, the opening(s) to facilitate bone ingrowth extend transversely through the implant and as such do not open in communication with the adjoining vertebrae. Thus, bone ingrowth and eventual fusion will occur more slowly.

Accordingly, a need exists for an improved wedge-shaped intervertebral implant which can be easily manufactured from a material which will be remodeled within the body and will more quickly become adherent to adjoining vertebrae.

SUMMARY

In accordance with the present disclosure, a ramp-shaped intervertebral implant which is constructed from animal or human cadaveric bone or bone composites, or from any biocompatible material having the requisite strength requirements suitable for implantation, is provided. The ramp-shaped implant includes a body having a first side, a second side and upper and lower surfaces. An opening extends through a central portion of the body between the upper and lower surfaces and a series of ridges are formed over at least a portion of at least one of the upper and lower surfaces. The implant decreases in height from the first end of the implant to the second end of the implant.

In a preferred embodiment, the implant is formed from the diaphysis or metaphysis of a long bone. More particularly, the implant is formed by first cutting a cortical ring from a long bone. Next, the cortical ring is secured within a holding fixture and the sidewalls of the cortical ring are machined to provide the implant with a desired shape. As such, the implant may retain its natural configuration or some or all of the sidewalls can be machined to form the implant to any configuration including rectangular, circular, C-shaped, etc. The intramedullary canal of the cortical ring defines an opening which extends from the top surface to the bottom surface of the implant. The implant is then placed in a second holding fixture and the top surface is machined to provide the appropriate taper and the ridges. These steps can be performed simultaneously using, for example, a three-dimensional computer operated milling machine. Alternately, the steps can be performed consecutively. Next, the implant is repositioned in the holding fixture and the bottom surface of the implant is machined to provide the appropriate taper and the ridges. The side surfaces may also be machined to vary the width of the implant along the longitudinal axis of the implant. A C-shaped implant can be formed by making a cut across the medial lateral plane of the cortical ring to expose the intramedullary canal. Thereafter, a ramp or taper can be provided in the anterior/posterior plane. Because the implant is constructed of bone, after insertion into the body of a patient, the implant will remodel within the body. New bone of a patient will eventually

replace some or all of the implant. Thus, if removal of the implant is ever necessitated, the implanted bone and/or the remodeled bone can be easily reamed out. Moreover, since the opening extends between the top and bottom surfaces of the implant, bone growth material which is packed into the opening directly contacts the adjoining vertebrae. Thus, fusion of the implant and adjoining vertebrae will occur more quickly.

Alternately, the ramp-shaped intervertebral implant can be formed from any biocompatible material having the requisite strength requirements via any known process including but not limited to molding and machining.

BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to the drawings wherein:

FIG. 1 is a perspective view of one embodiment of the presently disclosed ramp-shaped intervertebral implant;

FIG. 2 is a top view of the ramp-shaped intervertebral implant shown in FIG. 1;

FIG. 3 is a side view of the ramp-shaped intervertebral implant shown in FIG. 1;

FIG. 4 is a front view of the ramp-shaped intervertebral implant shown in FIG. 1;

FIG. 5 is a side view of a long bone with cut lines for cutting the cortical ring;

FIG. 6 is a perspective view of a cortical ring cut from the long bone shown in FIG. 5;

FIG. 7 is a perspective view of the cortical ring shown in FIG. 6 after the sidewalls have been machined;

FIG. 8 is a side view of the cortical ring shown in FIG. 6 after the sidewalls and the top surfaces have been machined;

FIG. 9 is a side view of the cortical ring shown in FIG. 6 after the sidewalls, the top surface and the bottom surface have been machined;

FIG. 10 is a perspective view of another embodiment of the ramp-shaped intervertebral implant;

FIG. 11 is a perspective view of yet another embodiment of the ramp-shaped intervertebral implant;

FIG. 12 is a perspective view of yet another embodiment of the ramp-shaped intervertebral implant;

FIG. 13 is a perspective view of yet another embodiment of the ramp-shaped intervertebral implant;

FIG. 14 is a top view of the intervertebral implant shown in FIG. 13;

FIG. 15 is a side view of the intervertebral implant shown in FIG. 13;

FIG. 16 is a perspective view of another embodiment of the ramp-shaped intervertebral implant;

FIG. 17 is a top view of the ramp-shaped intervertebral implant shown in FIG. 16;

FIG. 18 is a perspective view of another embodiment of the ramp-shaped intervertebral implant;

FIG. 19 is a top view of the intervertebral implant shown in FIG. 18;

FIG. 20 is a side view of an implant insertion tool; and

FIG. 21 is a perspective view of another embodiment of the ramp-shaped intervertebral implant.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed ramp-shaped intervertebral implant will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

FIGS. **1–4** illustrate one preferred embodiment of the presently disclosed ramp-shaped intervertebral implant shown generally as **10**. Ramp-shaped implant **10** includes a body **12** having a first wall **14**, a second wall **16**, a pair of sidewalls **18** and **20**, an upper surface **22** and a lower surface **24**. An opening **26** extends through body **12** from the upper surface **22** to the lower surface **24**. Opening **26** opens onto upper and lower surfaces **22** and **24** and is dimensioned to receive bone growth material including bone particles and/or a biocompatible osteoinductive or osteoconductive material.

Upper and lower surfaces **22** and **24** of body **12** converge from first wall **14** to second wall **16** and are configured to engage vertebral end plates after implantation. A series of ridges **28** are positioned on at least a portion of upper and lower surfaces **22** and **24**. Ridges **28** extend between sidewalls **18** and **20**. The apex of each ridge **28** defines a substantially right angle corner. Ridges **28** are configured to engage the adjoining vertebrae and prevent the implant from backing out of a receiving bed formed between the adjoining vertebrae. Alternately, in order to further prevent the implant from backing out of the intervertebral space, ridges **28** may be angled such that the apex of each ridge points towards second wall **16**. Moreover, protrusions other than ridges may be formed on the upper and lower surfaces of the implant, e.g., pyramid or semi-spherical protrusions.

Preferably, implant **10** is formed from cadaveric human or animal bone and/or bone composites. Such composites may include those discussed in U.S. Pat. No. 5,899,939 to Boyce et al. and in U.S. patent application Ser. No. 09/256,447 to Boyce et al., the entire disclosures of which are incorporated herein by reference. Alternately, other biocompatible materials can be used to form the implant. For example, surgical stainless steel, titanium, ceramic hydroxyopatite, polymers, carbon fiber, tantalum, etc., can also be used to construct the implant. Moreover, depending on the particular material used to construct the implant, a variety of different manufacturing procedures can be used to form the implant including machining and molding for example.

Referring to FIGS. **5–9**, in a preferred embodiment, the implant is formed from the cortical ring of a long bone, such as the fibula, radius, ulna, humerus, tibia or femur, by first making a pair of transverse cuts A and B across the diaphysis or metaphysis of a long bone C to form a cortical ring D. Typically, larger bone including humerus, tibia and femur are used to form implants for thoracic and lumbar spinal fusion procedures, whereas smaller bones including the ulna, radius and fibula are used to form implants for cervical spinal fusion procedures. Next, cortical ring D is secured within a holding fixture (not shown) and the sidewalls of the cortical ring are machined to provide a substantially rectangular implant E. Alternately, the sidewalls of the implant can be left to their natural configuration or the sidewalls can be machined to form an implant having a variety of other configurations, e.g., circular, triangular, etc. Subsequently, implant E is secured in a second holding fixture (not shown) and upper surface **22** is machined using a computer controlled three-dimensional milling machine to form ridges **28** and to angle the upper surface **22** from first end **14** to second end **16**, i.e., provide the taper. The angle is chosen to maintain the natural curvature of the spine. Alternately, a manually operated milling tool can be used to taper upper surface **22** and subsequently form ridges **28**. Next, implant E is repositioned in the second holding fixture and lower surface **24** is machined to form ridges **26** and to angle lower

surface 24 from first end 14 to second end 16. The intramedullary canal of the cortical ring defines opening 26. Alternately, the taper and ridges may be provided on only one of the upper and lower surfaces of the implant.

Typically, for thoracic and lumbar spinal fusion procedures, the implant has a length of from about 20 mm to about 21 mm, a width of from about 15 mm to about 18 mm, a rear end height of from about 9 mm to about 13 mm and a forward end height from about 11 mm to about 15 mm. For cervical spinal fusion procedures the implant has a length of from about 10 mm to about 15 mm, a width of from about 10 mm to about 15 mm, a rear end height of from about 6 mm to about 10 mm and a forward end height from about 8 mm to about 12 mm. Alternately, the dimensions of the implant may be varied to accommodate the particular procedure to be performed.

Preferably, before long bone D is cut, the bone is partially demineralized by placing the long bone in a 0.6NHCL solution. By demineralizing the bone in this fashion, only the walls of the intramedullary canal and the circumferential surfaces of the bone will be demineralized. The strength imparting surfaces of the ramp implant will not be compromised. Moreover, the bone may be treated using a variety of bone healing enhancing technologies. For example, bone growth factors may be infused into the natural porosity of the bone and/or the bone may be infused with acid to further demineralize the internal matrix of the bone. Both these bone treatments may be performed using the pressure flow system disclosed in U.S. Pat. No. 5,846,484 which is incorporated herein by reference.

FIGS. **10–12** illustrate alternate embodiments of the ramp-shaped bone intervertebral implant. FIG. **10** illustrates a substantially cylindrical ramp-shaped implant, shown generally as **100**. Implant **100** may be formed by machining the sidewall of a cortical ring (FIG. **6**) to provide a substantially cylindrical configuration. Alternately, the cortical ring need not be machined but rather, it may retain its natural shape, which depending upon the bone, may vary in shape from cylindrical to triangular in configuration. Implant **110** includes ridges **128** formed on its upper and lower surfaces. The upper and lower surfaces are also machined to taper the implant along its longitudinal axis from the first end **114** of the implant to the second end **116** of the implant.

In an alternate embodiment shown generally as **200** in FIG. **11**, the implant is tapered and ridges **228** are formed on only one of the upper and lower surfaces. The other surface **224** remains flat.

In another alternate embodiment shown generally as **300** in FIG. **12**, a portion of implant **200** is removed to form a substantially C-shaped ramp implant. C-shaped implant **300** includes an opening **326** and may include protrusions, such as ridges **328**, on either or both of the upper and lower surfaces of the implant. C-shaped implant **300** may form any portion of an arc from about 60° C. to 360°.

FIGS. **13–15** illustrate another alternate embodiment of the intervertebral implant shown generally as **400**. Intervertebral implant **400** is similar to implant **10** in all respects, except that sidewalls **418** and **420** are also angled to converge toward each other from first wall **414** to second wall **416** along the longitudinal axis of the implant. Implant **400** also includes a slot **450** which communicates with a threaded bore **452**. Slot **450** and threaded bore **452** are configured to mate with an implant insertion tool (not shown). Such a slot and threaded bore may be formed on each of the implants discussed above to facilitate insertion of the implant into the intervertebral space.

FIGS. **16–19** illustrate additional alternate embodiments of the ramp-shaped intervertebral implant. FIGS. **16** and **17** illustrate ramp-shaped intervertebral implant **500**. Implant **500** is substantially rectangular in shape as viewed from above (FIG. **17**). However, the upper and lower surfaces **522** and **524** are convex and include a series of ridges **528**. Intervertebral implant **600**, illustrated in FIGS. **18** and **19**, is substantially identical to implant **500**, except that sidewalls **618** and **620** have not been completely flattened as have sidewalls **518** and **520**.

Both intervertebral implants **500** and **600** include a first wall **514**, **614** having a threaded hole **550**, **650** and a pilot or threaded hole **552**, **652**. The holes are configured to engage a threaded prong **710** and a non-threaded prong **712** of an insertion tool **700** (see FIG. **20**). Insertion tool **700** facilitates insertion of the implant into the intervertebral space. The spacing of the pilot hole and the threaded hole may be varied on different implants such that only the proper insertion tool can be used to insert an implant into the intervertebral space. This will prevent inadvertent use of the wrong insertion tool with a particular implant. For example, this will prevent the use of instruments designed for inserting implants anteriorly with implants designed to be inserted posteriorly.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, rather than ridges, other protrusions may be formed on the upper and lower surfaces of the implant to retain the implant in a receiving bed formed between adjoining vertebrae. For example, the upper and lower surfaces may be knurled or include dimples or a variety of differently shaped projections. Moreover, any of the implants described above may include perforations **800** along any of its surfaces configured to receive bone growth material. See FIG. **21** for example. Further, the implant can be made using other known methods not disclosed in detail above, including molding and other machining processes. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirt of the claims appended hereto.

What is claimed is:

1. A ramp-shaped intervertebral implant comprising:

a body isolated from along bone having a first end, a second end and top and bottom surfaces, at least one of the top and bottom surfaces being tapered and converging towards the second end of the body, at least one of the top and bottom surfaces having a plurality of protrusions thereon, the protrusions defining substantially V-shaped elongated, parallel grooves, and at least one opening extending through the body having one end opening onto the top surface and one end opening onto the bottom surface, wherein the first end of the implant includes a threaded hole and a non-threaded hole, the holes being dimensioned to engage an insertion tool.

2. A ramp-shaped intervertebral implant according to claim 1, wherein the protrusions include a series of ridges.

3. A ramp-shaped intervertebral implant according to claim 2, wherein the implant includes a pair of substantially parallel side walls, each ridge of the series of ridges having a longitudinal axis that extends in a direction substantially perpendicular to the side walls.

4. A ramp-shaped intervertebral implant according to claim 1, wherein the implant is constructed from the diaphysis or metaphysis of a long bone and the intramedullary canal of the long bone defines the bore.

5. A ramp-shaped intervertebral implant according to claim 1, wherein the implant is formed from bone which is at least partially demineralized.

6. A ramp-shaped intervertebral implant according to claim 1, wherein the implant has a substantially rectangular configuration.

7. A ramp-shaped intervertebral implant according to claim 1, wherein protrusions are formed on both the top and bottom surfaces.

8. A ramp-shaped intervertebral implant according to claim 1, wherein at least one of the top and bottom surfaces is convex.

9. A method for forming a ramp-shaped implant comprising the following steps:

a) making a transverse cut across a long bone having an intramedullary canal to form a cortical ring;

b) machining at least one of top and bottom surfaces of the cortical ring such that the top and bottom surfaces of the cortical ring converge towards one another in a direction towards a second end of the cortical ring, at least one of the top and bottom surfaces having a plurality of substantially V-shaped elongated, parallel grooves, the intramedullary canal of the long bone defining an opening having one end opening onto the top surface of the cortical ring and having a second end opening onto the bottom surface of the cortical ring;

c) machining at least one of the top and bottom surfaces of the cortical ring to form a plurality of protrusions thereon; and;

d) forming a threaded hole and a non-threaded hole in a first end of the implant, the threaded hole and non-threaded hole being dimensional to engage an insertion tool.

10. A method for forming a ramp-shaped implant according to claim 9, wherein the protrusions include a series of ridges.

11. A method for forming a ramp-shaped implant according to claim 10, wherein the machining steps further include use of a three-dimensional milling machine.

12. A method for forming a ramp-shaped implant according to claim 11, wherein steps c) and d) are performed simultaneously using the three-dimensional milling machine.

13. A method for forming a ramp-shaped implant according to claim 9, further including the step of partially demineralizing the bone.

14. A method for forming a ramp-shaped implant according to claim 13, wherein the step of partially demineralizing the bone occurs before the cortical ring is cut from the long bone.

15. A method for forming a ramp-shaped implant according to claim 9, further including the step of:

d) machining sidewalls of the cortical ring to form an implant having a substantially rectangular configuration.

16. A method for forming a ramp-shaped implant according to claim 9, further including the step of:

d) infusing bone growth material into the bone.

17. A method of forming a ramp-shaped implant according to claim 9, further including the step of:

d) forming a plurality of perforations in surfaces of the implant other than the top and bottom surfaces.

18. A method of forming a ramp-shaped implant according to claim 9, wherein at least one of the top and bottom surfaces is convex.

19. A method for forming a ramp-shaped implant comprising the following steps:

a) making a transverse cut across a long bone to form a cortical ring;

b) machining at least one of the top and bottom surfaces of the cortical ring to taper the cortical ring from a first end of the cortical ring to a second end of the cortical ring and to provide a plurality of substantially V-shaped elongated, parallel grooves, the intramedullary canal of the long bone defining an opening having one end opening onto the top surface of the cortical ring and having a second end opening onto the bottom surface of the cortical ring;

c) machining at least one of the top and bottom surfaces of the cortical ring to form a plurality of protrusions thereon; and

d) infusing bone growth material into the bone.

* * * * *

US005888227A

United States Patent [19]

Cottle

[11] Patent Number: 5,888,227

[45] Date of Patent: Mar. 30, 1999

[54] INTER-VERTEBRAL IMPLANT

[75] Inventor: William Cottle, Vancouver, Canada

[73] Assignee: Synthes (U.S.A.), Paoli, Pa.

[21] Appl. No.: 11,011

[22] PCT Filed: Oct. 3, 1996

[86] PCT No.: PCT/CH96/00346

§ 371 Date: Feb. 2, 1998

§ 102(e) Date: Feb. 2, 1998

[87] PCT Pub. No.: WO97/15248

PCT Pub. Date: May 1, 1997

[30] Foreign Application Priority Data

Oct. 20, 1995 [WO] WIPO PCT/CH95/00245

[51] Int. Cl.[6] A61F 2/44

[52] U.S. Cl. 623/17

[58] Field of Search 623/17; 606/61

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WO95/32673	12/1995	WIPO .

Primary Examiner—Michael J. Milano

Attorney, Agent, or Firm—Pennie & Edmonds LLP

[57] ABSTRACT

An inter-vertebral implant having of a frame-like cage (1) enclosing a space (20), with a top and bottom surface (11,12), two side surfaces (13, 14), a front (16) and a rear wall (15). The top and bottom surfaces (11, 12) have a plurality of perforations (24), the total area of which amounts to 40 to 55% of the total area of said surfaces (11, 12). The individual area of a single perforation (24) is at most 20% of the total area of the top and bottom surfaces (11, 12). The ratio VH/VK between the volume VH of the space (20) and the total volume VK of the cage (1) is in the range from 70 to 90%. The cage (1) is substantially wedge-shaped with top and bottom surfaces (11, 12) diverging towards the front wall (16). This gives the advantage that, owing to the large bone bearing area of the top and bottom surfaces, the implant is prevented from sinking into the end plates of the body of the vertebra.

22 Claims, 2 Drawing Sheets

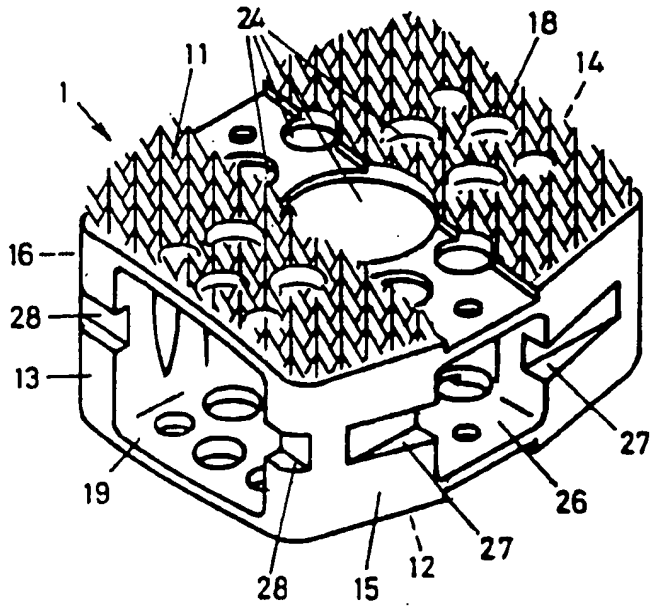


Fig. 1

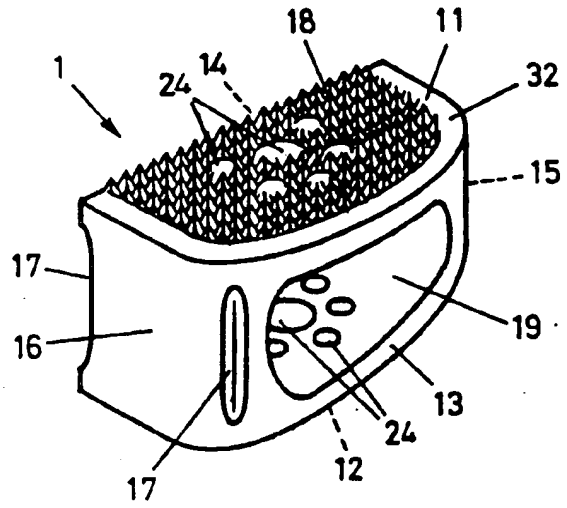


Fig. 2

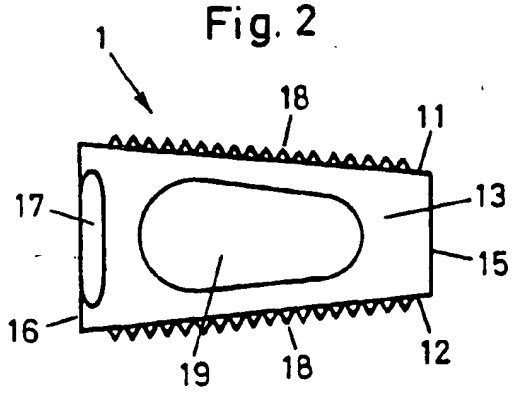


Fig. 3

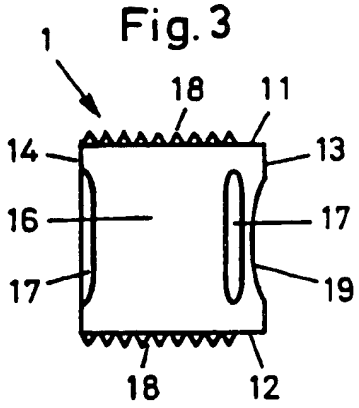


Fig. 4

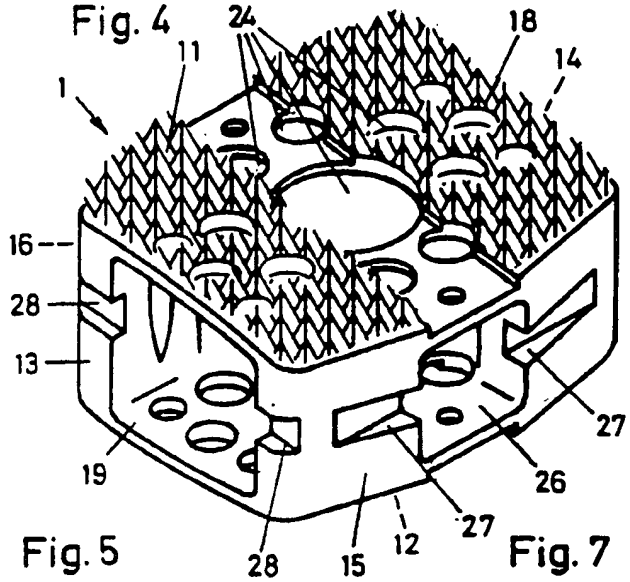


Fig. 5

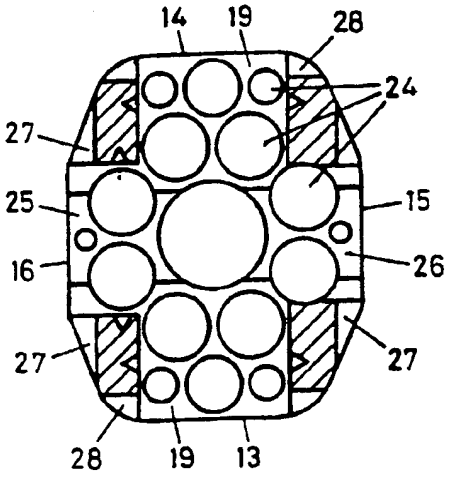


Fig. 7

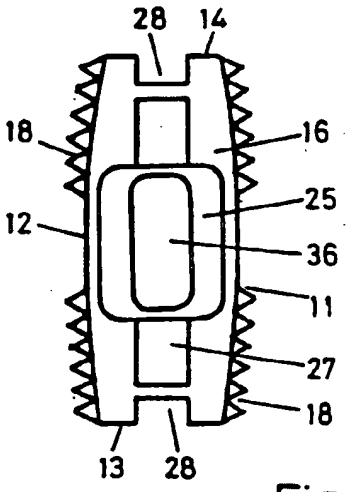


Fig. 8

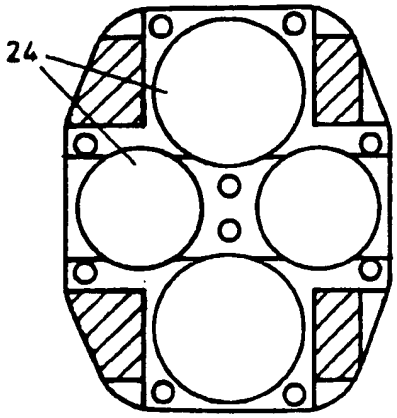
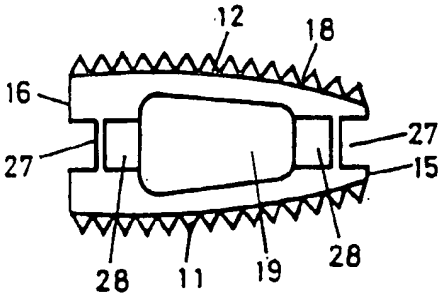


Fig. 6



INTER-VERTEBRAL IMPLANT

TECHNICAL FIELD

The invention relates to an intervertebral implant having a frame-like cage, perforated cover and base faces, two lateral surfaces and front and rear walls, where at least one of the cover or base face has a plurality of perforations.

BACKGROUND ART

Intervertebral implants are used for the fusion of two vertebral bodies, especially in the area of the lumbar spine. One or two implants are used for each intervertebral space.

Various types of such intervertebral implants are already known from the prior art. However, all of these have the disadvantage that they harbor the risk of the implant sinking into the end plates of the affected vertebrae. For example, an intervertebral implant in the form of a ring or double ring open on top and bottom is known from the U.S. Pat. No. 5,192,327 BRANTIGAN. Since only the edge of the ring implant and at most also the narrow connection web in the case of a double ring design can act as bone contact surface, there is considerable risk that the end plates of the thereby spaced-apart vertebral bodies will sink in.

SUMMARY OF THE INVENTION

The invention is intended to remedy this. It is an object of the invention to create an intervertebral implant which can be inserted into the intervertebral space in a controlled manner, which has an optimal bone contact surface, and, due to a number of perforations in the bone contact surface, nevertheless promotes good ingrowth behavior on the part of the bone.

This object is achieved by the use of an intervertebral implant having a frame-like cage which is essentially wedge shaped, encloses a cavity and has perforated cover and base faces as bone contacting surfaces, along with two lateral surfaces, and front and rear walls. The cover and base faces diverge toward the front wall, and at least one of those faces includes a plurality of perforations whose total area makes up 40 to 55% of the total area of that face. The individual area of an individual perforation is at most 20% of the area. Also, the ratio of cavity volume to cage volume is preferably in the range of 0.11 to 0.42.

This achieves the advantage that, due to the large bone contact surface of the cover and base faces, the implant is prevented from sinking into the end plates of the vertebral bodies.

However, at the same time a number of perforations in the cover and/or base face allow the bone to grow in. The perforations in the cover and/or base face are extremely important for the bone to grow in, which causes the adjoining vertebral bodies to fuse. Surprisingly, it has appeared that the geometrical relationships of these perforations have decisive significance for clinical success. If the total area of these perforations is too small, the bone cannot grow in to the required extent so that fusion does not occur. On the other hand, if the total area of these perforations is too large, the remaining contact surface of the cover and base faces of the implants relative to the end plates of the adjoining vertebral bodies is too small, which results in excessive contact forces between the implant and the end plates, which again increases the risk that the implant will sink into the end plates.

It has appeared that the total area of the perforations in the cover and/or base face must lie in the range of 40–55% of the total area of the cover and/or base face, in order to achieve good clinical results. The total area of the perforations in the cover and/or base face preferably should be 43–51%, typically 45–49% of the total area of the cover and/or base face.

The dimensions of the individual perforations in the cover and/or base face have also proven to be very important for the degree of clinical success. If the area of the individual perforations is too small, it becomes more difficult for the bone to grow in, even though the total perforation area may be considerable. On the other hand, perforations in the cover and/or base face with too great an average area also have a negative effect, because they impair the uniform support of the end plate, thus creating a risk of the implant locally sinking into the end plate. It has appeared that the individual area of an individual perforation may amount at most to 20% of the total area of the cover and/or base face, in order to achieve good clinical results. The individual area of an individual perforation preferably should amount to 5–15%, typically 8–13% of the total area of the cover and/or base face.

The diameter of the perforations preferably should be at most 9.0 mm, typically at most 5.0 mm. The perforations affixed in the edge region of the cover and/or base face should on the average be smaller than the perforations affixed in the central region of the cover and/or base face, preferably with a gradual increase of diameter from outside to inside. The result of this is that the centrally affixed perforations permit the bone to grow in at the thinnest—and best suited—point of the end plate, while on the other hand the peripheral part of the cover and/or base face yields the best contact surface relative to the more dense edge part of the bony end plate.

Finally, it has also appeared that the geometrical relationships of the implant, which is designed as a hollow body, are important for clinical success. In order to be able to achieve good fusion of the adjoining vertebrae, it is necessary to keep the ratio VH/VK between the volume of the hollow space VH and the total volume VK of the cage in a high range of 70–90%. This guarantees that bone chips or bone replacement materials can be introduced easily, which offers the first optimal preconditions for fusion. The ratio VH/VK between the volume of the hollow space VH and the total volume VK of the cage preferably should lie in the range of 75–85%, typically 78–82%.

In a preferred embodiment, with a three-dimensional structure of the cover and base faces of the cage, high positional stability of the implant is also achieved. The three-dimensional structure can consist of teeth, longitudinal grooves, or other suitable elevations or depressions. The height of these structures should amount to 0.5–2.0 mm, preferably 1.0–1.5 mm. For example, the structure can consist of teeth, preferably in a regular arrangement.

The three-dimensional structure can be a structured hydroxyl apatite coating. It is also possible to coat the entire cage with hydroxyl apatite or with another bioactive material.

However, the three dimensional structure can also be a structural coating consisting of titanium, titanium alloys, or other physiologically compatible metals.

The cover and base faces preferably have a free edge without structurization.

In another embodiment, the cover and base faces are designed so as to bulge convex outward, so as to achieve optimal matching to the geometry of the end plates of the adjoining end plates of the vertebral bodies.

In another embodiment, the lateral faces also have perforations, whose total area should amount at most to 40% (typically at most to 30%) and at least to 15% (typically at least 20%) of the total area of the side faces. The perforations in the side faces preferably are longitudinal hole recesses.

The front wall can also have perforations, preferably in the form of longitudinal recesses.

In another embodiment, the front wall has means for receiving an instrument, by means of which the cage can be manipulated. The side faces also can have means for receiving an instrument, by means of which the cage can be manipulated.

In another embodiment of the invention, two intervertebral implants are joined to form a combination implant, with the two intervertebral implants being integrally joined to one another at their missing lateral faces. The combined front wall preferably has a longitudinal hole recess.

The inventive implant has the following advantages relative to the prior art:

a) secure against slipping;

b) improved x-ray transparency; due to the perforations in the lateral faces, as well as in the front and rear wall, the fusion behavior of the implant can easily be checked radiologically, which is greatly hindered in the case of implants according to the prior art, with closed lateral faces;

c) compressibility of bone material which may be introduced into the cage.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention and further developments of the invention are explained in more detail below by means of the partially schematic representations of several embodiments.

FIG. 1 shows a view, in perspective, of the inventive implant.

FIG. 2 shows a longitudinal section through the implant of FIG. 1.

FIG. 3 shows a cross section through the implant of FIG. 1.

FIG. 4 shows a view, in perspective, of a variation of an inventive implant.

FIG. 5 shows a top view of the implant of FIG. 4.

FIG. 6 shows a side view of the implant of FIG. 4.

FIG. 7 shows a view of the rear side of the implant of FIG. 4.

FIG. 8 shows a top view of a modified implant in accordance with FIG. 4.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The intervertebral implant shown in FIGS. 1–3 essentially consists of a frame-like cage 1, closed at its cover face 11 and base face 12 (except for perforations), with two lateral faces 13 and 14, each of these having a longitudinal hole 19, a front wall 16 which has two grooves 17, and a rear wall 15. The grooves 17 serve to receive a manipulation instrument. The cage 1 is wedge-shaped, i.e. with cover and base faces 11, 12 which diverge toward the front wall 16.

In the design of FIGS. 1–3, the cover and base faces 11, 12 have a three-dimensional structure 18, preferably in the form of pointed teeth in a regular arrangement, with a height of about 1.75 mm, so as to improve the positional stability of the implant. The cover and base faces 11, 12 have a free edge 32 without such a structure 1. The free edge 32 reduces the risk of injury during and after the operation.

The cover and base faces 11, 12 have a plurality of perforations 24, whose total area amounts to 40% of the total area of the cover and base faces 11, 12. The individual area of an individual perforation 24 amounts to 15% of the total area of the cover and base faces 11, 12. The ratio VH/VK between the volume VH of the hollow space 20 and the total volume VK of the cage 1 amounts to 0.22.

As FIG. 1 shows, the front wall 16 of the cage 1 has two grooves 17 to receive an instrument, so that the cage 1 can be inserted into the intervertebral space and can be positioned there.

FIG. 4–8 show other embodiments of the invention. Apart from the modifications described below, these have the same features as the embodiment of FIGS. 1–3. The inventive implant consists of a frame-like cage 1 with a cover face 11, a base face 12, two lateral faces 13 and 14, each having a longitudinal hole 19, a front wall 16, having an aperture 25, and a rear wall 15 having an aperture 26. The aperture 25 has lateral grooves 27, which can accept a suitable manipulation instrument. The longitudinal holes 19, which are positioned in the lateral faces 13, 14, also have lateral grooves 2, which can accept a suitable manipulation instrument.

The cage 1 is wedge-shaped, i.e. with cover and base faces 11, 12 which diverge toward the front wall 16.

In the embodiment of FIGS. 4–7, the cover and base faces 11, 12 have a plurality of perforations 24. The total area of these perforations is 48% of the total area of the cover and base faces 11, 12. The individual area of an individual perforation 24 amounts to 10% of the total area of the cover and base faces 11, 12. The ratio VH/VK between the volume VH of the hollow space 20 and the total volume VK of the cage 1 amounts to 0.21.

The perforations 24 in the cover and base faces 11, 12 of the implant can be varied in many respects—within the inventive range. For example, FIG. 8 shows a variation of the perforations 24 in the cover and base faces 11, 12 of the implant of FIG. 4. Here, the total area amounts to 50% of the total area of the cover and base faces 11, 12. The individual area of an individual perforation 24 amounts to 15% of the total area of the cover and base faces 11, 12. The ratio VH/VK between the volume VH of the hollow space 20 and the total volume VK of the cage 1 is 0.22.

In all the embodiments, the cage 1 can be made of titanium, titanium alloy, ceramic, or a biocompatible plastic, e.g. polyethylene.

The clinical application will now be described in detail below.

The cage 1 shown in FIG. 1 is filled with bone chips (bone graft) or bone replacement material, possibly under compression, through the lateral perforations 19 in the form of longitudinal hole recesses. Then the filled cage 1 is pushed into the cleared intervertebral space with the help of a distending instrument. A tool, which is inserted into the two grooves 17 in the front wall 16 of the cage 1, can here be used as a manipulator.

The cage 1 can be formed either as a semi-implant, as shown in FIGS. 1–3, so that two implants must be inserted into the intervertebral space, or else it is also possible to form two semi-implants integrally, as shown in FIGS. 4–7, so that only one implant must be inserted into the intervertebral space.

What is claimed is:

1. An intervertebral implant comprising a frame-like cage which is essentially wedge-shaped, encloses a cavity, and which has perforated cover and base faces as bone-contacting surfaces, two lateral surfaces, and front and rear walls, wherein the cover and base faces diverge toward the front wall, and at least one of the cover face or base face has a plurality of perforations whose total area makes up 40 to 50% of the total area of the cover face or base face; with each individual perforation having an area amounting at most to 20% of the total area of the cover face or base face; and wherein the cavity has a volume VH, the cage has a volume VK, and the ratio of VH/VK is from 0.11 to 0.42.

2. The implant of claim 1, wherein the cover and the base faces are provided with a three-dimensional structure.

3. The implant of claim 1, wherein the cover and base faces each include a central region surrounded by an edge region, and the perforations affixed to the edge region of the cover or base face, on average, are smaller than the perforations affixed to the central region of the cover or base face.

4. The implant of claim 1, wherein the cover and base faces are configured to bulge outward.

5. The implant of claim 1, wherein the perforations have a maximum diameter of 9 mm.

6. The implant of claim 1, wherein the lateral faces have perforations whose total area is at most 40% of the total area of the lateral faces.

7. The implant of claim 6, wherein the lateral faces (13, 14) have perforations whose total area is at least 15% of the total area of the lateral faces.

8. The implant of claim 2, wherein the three-dimensional structure is a structured hydroxyl-apatite coating.

9. The implant of claim 2, wherein the three-dimensional structure is a structured coating of titanium or a titanium alloy.

10. The implant of claim 2, wherein the three-dimensional structure comprises a regular arrangement of teeth.

11. The implant of claim 2, wherein the three-dimensional structure has a height of 0.5–2.0 mm.

12. The implant of claim 1, wherein the front wall has means to receive an instrument for manipulating the cage.

13. The implant of claim 1, wherein each lateral face has means to receive an instrument for manipulating the cage.

14. The implant of claim 1, wherein the cover face and the base face each has an edge which is free of three dimensional structure.

15. The implant of claim 1, wherein the perforations in the lateral faces are longitudinal holes.

16. The implant of claim 1; wherein the front wall is equipped with perforations in the form of longitudinal holes.

17. The implant of claim 1, wherein the cage is coated with hydroxylapatite.

18. The implant of claim 1, wherein each individual perforation has an area which constitutes 5–15% of the total area of the cover or base face.

19. The implant of claim 1, wherein the ratio of VH/VK ranges between 0.17 and 0.33.

20. The implant of claim 1, wherein the total area of the perforations in the cover or base face amount to 43–51%.

21. A combination implant with two intervertebral implants in accordance with claim 1, wherein the two intervertebral implants are joined integrally together at their lateral faces.

22. The combination of implant of claim 21, wherein the combined front wall has a longitudinal hole recess.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,888,227
DATED : March 30, 1999
INVENTOR(S) : William Cottle

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 5, line 9, change "50" to --55--.

Signed and Sealed this

Eleventh Day of May, 1999

Attest:

Attesting Officer

Q. TODD DICKINSON

Acting Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,888,227

DATED : March 30, 1999

INVENTOR : William Cottle

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 1, Column 5, line 8, please delete 50% and insert --55%--.

Signed and Sealed this

Twenty-first Day of September, 1999

Attest:

Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks

US005865845A

United States Patent [19]

Thalgott

[11] Patent Number: 5,865,845

[45] Date of Patent: Feb. 2, 1999

[54] **PROSTHETIC INTERVERTEBRAL DISC**

[76] Inventor: **John S. Thalgott**, 600 S. Rancho, Ste 107, Las Vegas, Nev. 89106

[21] Appl. No.: **609,593**

[22] Filed: **Mar. 5, 1996**

[51] **Int. Cl.**[6] **A61F 2/44**

[52] **U.S. Cl.** **623/17**

[58] **Field of Search** 623/17, 16; 606/60, 606/61

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Primary Examiner—Debra S. Brittingham

Attorney, Agent, or Firm—Cooper & Dunham LLP

[57] **ABSTRACT**

The invention provides a spinal disc implant comprising a ring shaped body including a first pair of opposed substantially parallel sides spaced apart by a second pair of opposed sides to define a central bore. A first one of the second pair of sides defines a substantially arcuate curve joining a first end of the first pair of sides. A second one of the second pair of opposed sides substantially linearly joins a second end of the first pair of sides. The upper and lower surfaces of the ring shaped body have a plurality of teeth extending therefrom for engaging adjacent vertebrae. The implant is made of a biocompatible metal such as titanium or an alloy thereof, and the first and second sides tapering from the second end to the first end. The interior space may have a porous hydroxyapatite block shaped to fill the interior space. The porous hydroxyapatite substance helps the prosthesis integrate into the vertebral structure by allowing one grow into the pores.

9 Claims, 1 Drawing Sheet

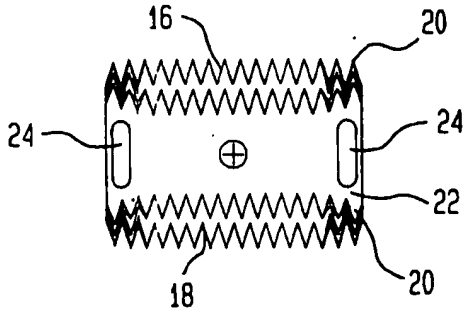


FIG. 1

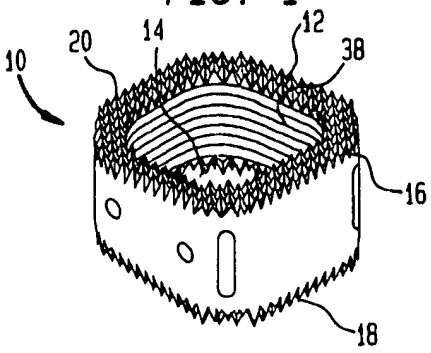


FIG. 2

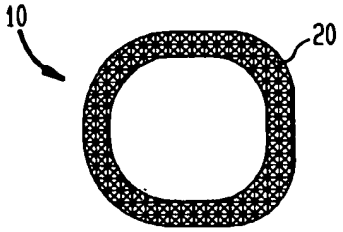


FIG. 3

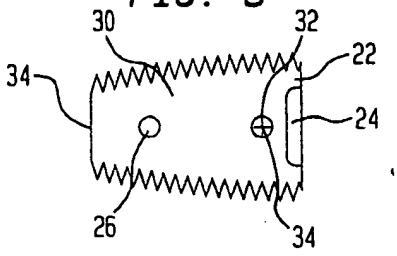


FIG. 4

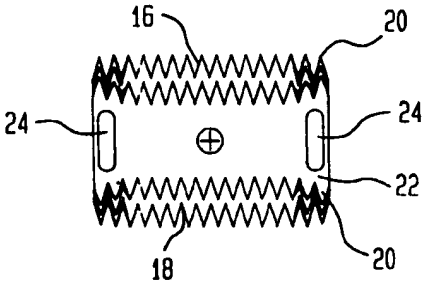


FIG. 5

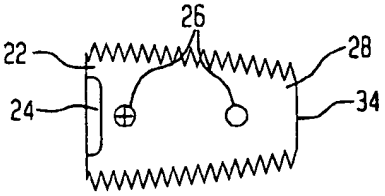


FIG. 6

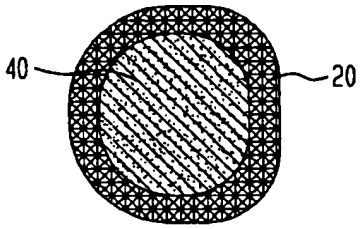


FIG. 7

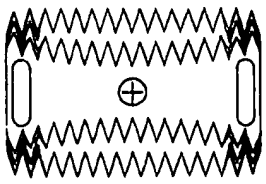


FIG. 8

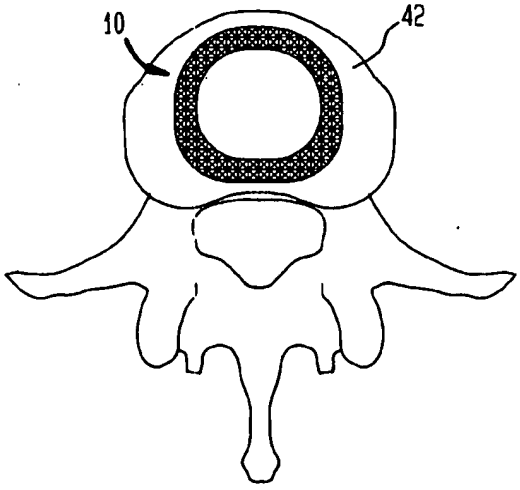
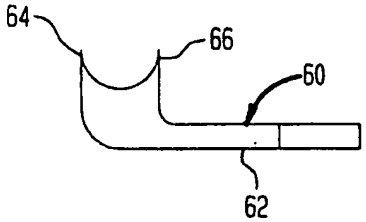


FIG. 9



PROSTHETIC INTERVERTEBRAL DISC

FIELD OF THE INVENTION

This invention relates to artificial biocompatible vertebral synthetic devices and more particularly to prosthetic metal intervertebral discs, and methods and tools for implanting such prostheses.

BACKGROUND OF THE INVENTION

Many types of vertebral prostheses have been proposed and patented for implantation in the vertebral disc space after surgical removal of a diseases or damaged disc. Such devices fall into several broad categories. One category includes prostheses advocates the use of pliable synthetic materials in an attempt to mimic the compressibility of the natural human spinal disc. For example, U.S. Pat. No. 5,171,281 (Parsons) discusses a disc spacer which purports to possess mechanical properties akin to those of the normal disc by varying the hardness of the elastomeric material in its nucleus and annulus. U.S. Pat. No. 5,192,326 (Bao) illustrates a prosthetic disc formed from a multiplicity of hydrogel beads having a water content of at least 30%. A semi-permeable membrane covers the beads and is said to permit fluids to flow in and out of the prosthetic nucleus. U.S. Pat. No. 5,071,437 (Steffee) has another approach to a pliable implant. That approach involves upper and lower flat rigid plates sandwiching an elastomeric core made from a polyolefin rubber. U.S. Pat. No. 5,002,576 (Fuhrmann) also discusses a variant on the foregoing approach.

Another approach involves attempts to mimic the shape of a natural spinal disc. U.S. Pat. No. 4,714,469 (Kenna) discusses a spinal implant adapted to replace a disc between adjacent vertebrae using a predetermined thickness and profile to match the space between the vertebrae. The implant includes a porous coating on its surface. U.S. Pat. No. 4,759,766 (Buettner-Janz) illustrates a metallic disc endoprosthesis which has two symmetrical, concave end plates with an intermediate spacing piece. Similarly, U.S. Pat. No. 5,314,477 (Oka) discusses a disc prosthesis including two plates separated by a joint composed of a spherical cap and cylindrical base which attempts to ensure connection between the vertebrae.

Some prostheses emphasize mimicking the shape of the space formed by adjacent vertebral bodies. For example, according to the patentee of U.S. Pat. No. 5,320,644 (Baumgartner), he provides a disc prosthesis having a wedge shape having a wedge angle from the ventral to the dorsal side. The patent says the disc has parallel slits arranged at a right angle to its axis which partly overlap one another, forming leaf springs for transmission of forces from one attachment surface to another. U.S. Pat. No. 5,306,309 (Wagner) provides a spinal disc implant having a right rectangular body including two opposed side faces and two opposed transverse faces. According to the patentees, a convexly curved anterior face defines one end of the right rectangular body, and an outwardly curved face of about that of the anterior surface of a human vertebra.

Each of the foregoing prostheses, however, while addressing some problems, presents others. It is therefore a principal object of the invention to provide a disc prosthesis whose design takes into consideration the anatomy and particularly the geometry of the intervertebral space sought to be filled by the prosthetic device. It is an important and further object to provide a spinal disc prothesis which integrates well with the vertebral bone tissue of adjacent vertebral bodies between which the device is inserted.

SUMMARY OF THE INVENTION

The foregoing objects are achieved and the disadvantages of the prior art are overcome by providing a spinal disc implant comprising a first pair of opposed substantially parallel sides spaced apart by a second pair of opposed sides to define an interior space. A first one of the second pair of sides defines a substantially elliptical curve joining a first end of the first pair of sides. A second one of the second pair of opposed sides substantially linearly joins a second end of the first pair of sides. The upper and lower edges of the implant have a plurality of teeth extending therefrom for engaging adjacent vertebrae. The implant is made of a biocompatible metal such as titanium or an alloy thereof, and the first and second sides tapering from the second end to the first end.

Preferably, the interior space has a porous hydroxyapatite block shaped to fill the interior space. The porous hydroxyapatite substance helps the prosthesis integrate into the vertebral structure by allowing bone grow into the pores.

BRIEF DESCRIPTION OF THE DRAWINGS

Other features and advantages of the invention will be apparent from the following detailed description of the preferred embodiments taken in conjunction with the accompanying drawings in which:

FIG. **1** is a perspective view of the spinal disc implant of the present invention;

FIG. **2** is a top view of the spinal disc implant of FIG. **1**;

FIG. **3** is a view of one side of implant of FIG. **1**;

FIG. **4** is a front view of the spinal disc implant of FIG. **1**;

FIG. **5** is a side view of the spinal disc implant of the side opposite from FIG. **3**;

FIG. **6** is a rear view of the spinal disc implant of FIG. **1**;

FIG. **7** is a top view of another preferred embodiment of the spinal disc implant of FIG. **1**, wherein the open portion is filled with porous hydroxyapatite; and

FIG. **8** is a plan view of a cervical vertebra with the spinal disc implant of FIG. **1** shown in phantom (dashed) lines positioned thereon.

FIG. **9** is plan view of an implantation tool for use in implanting the spinal disc implant of FIG. **1**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates a spinal disc implant of the present invention generally indicated by the reference numeral **10**. The implant **10** has a generally D-shaped body **12** including a central opening **14**. The implant further **10** includes first and second faces **14, 16** having a plurality of teeth **20** or other gripping means included on each face.

Referring to FIG. **4**, the front side of the implant **22** has at either edge thereof a pair of vertical oval shaped slots **24** used for gripping and positioning the implant **10** during surgery. The implant **10** additionally has one or more central circular notches **26** which a prong of a surgical tool (not shown) can engage to help position the implant **10**. The first lateral side **28** of the implant **10** (illustrated in FIG. **5**) includes two circular notches or dimples **26** to engage a pair of prongs **(64, 66)** for a surgical implantation tool **60**, shown in FIG. **9**. FIG. **3** illustrates or shows a second lateral side **30** which includes a notch **26** and a hole into which a set screw **34** is tightened so that it is flush with the surface of the second lateral side **30**, as shown in FIG. **3**. The rear side of

the implant **35** includes a hole **36** similar to the one discussed in connection with the second lateral side **30**. Once again, a set screw **34** is tightened into the hole **36** so that it is flush with the surface of the rear side **35**. The interior surface **38** of the implant (see FIG. **1**) has a series of circumferential scorings **40** to help hold by friction any material inserted in the central opening **14**.

The teeth **20** (best shown in FIG. **2**) are preferably steeply sloped four-sided pyramids arranged in straight rows across and down the first and second faces **16, 18** of the implant **10** as shown in FIG. **2**. The pyramidal faces preferably form a 45° angle with the vertical. They can be formed by machining the implant **10**.

An important aspect of the present invention is its geometric compatibility with its environment Referring to FIGS. **3** and **5**, the implant **10** slopes from the front or anterior side **22** to the rear or posterior side **34**. This shape enables the implant **10** to fit between adjacent vertebral bodies **42** (see FIG. **8**) when the spine is in an upright position. The exact angle formed at the vertex defined by the first and second faces **16, 18** varies depending on which disc is being replaced. In the lumbar region of the spine, for example, the opposed faces adjacent vertebral bodies define an angle ranging from about 0 to about 20degrees. Similarly, since the vertebral body **42**, which engages the first and second faces **16, 18** from above and below, has curvature, the implant **10** also has curvature to allow it to conform to the domed shape the vertebral body surface.

The implant 10 is preferably made from pure titanium or an alloy thereof, preferably anodized to increase its biocompatiblity by making it more inert. The implant **10** may be made from bar stock, or tubing or by molding; or from titanium powder using powder metallurgy technique. The dimensions of the implant **10** vary depending on where in the spine the implant will be inserted. The vertebral bodies in the lumbar area of spine, for example, are larger than the vertebral bodies in the thoracic area. Therefore, an implant intended for the thoracic region would be smaller than one for the lumbar region. Likewise, lower lumbar disc replacements would be larger than upper ones. By way of example, an implant sized for implantation between the third and fourth lumbar vertebrae may be 2.7 cm. long, 2.5 cm wide, about 2 cm high anteriorly, and sloping down to about 1.3 cm high posteriorly. A person of ordinary skill could adapt the basic dimensions of the implant to make them occupy for the space formerly occupied by the particular vertebral disc which needs replacement.

The shape and curvature of the first and second faces **16, 18** of the implant **10** provide several advantages. In the lumbar region of the spine, the discs and vertebral bodies **42** are held at an angle creating a lordosis or curvature of the lumbar spine. To have the implant **10** be parallel or coplanar would be physiologically and anatomically unacceptable. The natural discs in the lumbar spine are wider anteriorly than they are posteriorly. The disc replacement implant **10** of the present invention is therefore also wider anteriorly than it is posteriorly. This recreates the natural anatomic curvature of the spine.

Further, the implant **10** of the present invention takes into consideration the anatomy of the undersurface of the vertebral body or end plate of the vertebra on which the second face **18** of the implant **10** rests. The end plate is made of very compact bone circumferentially, but as the bone centralizes towards the middle, it becomes thinner. The thinner portion is dome shaped, and is responsible for the hydraulic stress transmission between the vertebral body and the disc itself. The dome shaped middle of the end plate is mimicked by the secondary curvature in the disc implant of the present invention. The secondary arc which corresponds to the dome in the vertebral body provides a mechanism to lock the cage in place and prevent slippage or extrusion. The teeth **20** on the first and second faces **16, 18** of the implant **10** grip the vertebral body and cause a mechanical interface between the prosthesis **10** and the end plate of the vertebral body **42**.

In another embodiment, depicted in FIG. **6**, the implant **10** includes an insert of synthetic bone material **50**, such as porous hydroxyapatite or other equivalent substance. Preferably, the synthetic bone material **50** is Interpore ProOsteon 500 brand of porous coralline hydroxyapatite, available from Interpore International, Irvine Calif. The porous synthetic bone material **50** is held in place by press fit (friction) and by the set screws **34** on the sides of the implant **10**. The porous synthetic bone **50** allows independent placement of the implant **10** into the intervertebral disc space without use of a bone graft. This will prevent the morbidity and complications associated with harvesting a bone graft from the patient, reported to be as high as 21%. It will also obviate the need for use of an allograft, which carries the risk of disease transmission and added expense.

The implant **10** provides a non-articulating disc prosthesis which can be provided in multiple sizes depending on the size needed for the specific lumbar region, and can be furnished in smaller sizes for the cervical and thoracic spine as well as miniature cages for placement using endoscopic techniques for minimally invasive spine surgery.

The invention also provides a tool **60** (FIG. **9**) for use in implanting an implant **10** in accordance with the present invention. The tool **60** includes a handle **62** and a pair of spaced arms **64, 66** extending perpendicularly therefrom. The arms **64, 66** are spaced to engage a pair of dimples **26** on an implant **10** or the oval slots **24**. To use the tool, the surgeon merely inserts the arms **64, 66** into the notches **24** or dimples **26** until the implant **10** is held by the tool **60** and can be lifted. The implant **10** and the tool **60** can be furnished in kit form in a presterilized or sterilizable package (not shown).

During implantation surgery, the surgeon exposes the herniated or damaged disc, and removes it. A spinal disc implant **10** including a central core of porous synthetic bone, such as Interpore ProOsteon 500, is inserted using tool **60**. The tool **60** grips the implant **10**, which enables the surgeon to lift and insert the implant **10** in the intevertebral space defined by adjacent vertebral bodies from which the damaged or diseases disc was removed. The implant **10** is positioned on the vertebral body **42** (see FIG. **8**) so that its transverse curvature conforms to the dome shape of the vertebral body **42**. At the same time, the implant **10** is positioned so that its anterior to posterior position will create the proper angulation between vertebrae to help to restore the natural anatomic curvature of the human spine. The implant **10**, once implanted, encourages osseointegration in two distinct ways. The teeth **20** found an irregular surface which grip the vertebral body and allow bone tissue to ground in and around the teeth **20**. Also, the synthetic porous bone segment allows bone tissue to grow into the pores, to help anchor the implant **10** in place without resorting to bone grafts or allografts.

The following example is illustrative of the practices of the invention, and is not to be considered limiting.

EXAMPLE

A spinal disc implant **10** in accordance with the present invention implanted was implanted in the lumbar region

spine of a patient. The implant additionally had porous synthetic bone (Interpore ProOsteon 500) in the central space, and pins were placed in the vertebrae above and below the implant **10** as an extra precaution to help insure that the implant **10** was securely held in place and that portion of spine did not articulate. To date this patient had no evidence of radiographic non-union and has had a satisfactory clinical outcome based upon range of motion, decreased pain, and return to prior activities.

Various modifications will be apparent to those skilled in the art. Such modifications and changes are intended to be included within the scope of the invention, which is defined by the following claims.

I claim:

1. A spinal disc implant comprising a ring-shaped body including a first pair of opposed substantially parallel sides spaced apart by a second pair of opposed sides to define a central bore, a first one of the second pair of sides defining a substantially arcuate curve joining a first end of the first pair of sides, a second one of the second pair of opposed sides joining a second end of the first pair of sides, upper and lower surfaces of the ring-shaped body having a plurality of teeth extending therefrom along a perimeter of the implant for engaging the adjacent vertebral bodies, the implant being made of a bicompatible metal; the first and second sides tapering from the second end to the first end and conforming to a curvature of a vertebral body on which the implant rests.

2. A spinal disc implant in accordance with claim **1** wherein the ring-shaped body is substantially oval.

3. A spinal disc implant in accordance with claim **1** wherein the ring-shaped body is substantially D-shaped.

4. A spinal disc implant in accordance with claim **3** wherein the biocompatible metal is titanium or alloys thereof.

5. A spinal disc implant in accordance with claim **3** wherein the central bore includes a porous hydroxyapatite block shaped to fill the central bore.

6. A spinal disc implant in accordance with claim **5** wherein the upper and lower surfaces of the ring-shaped body are convexly curved to mate with surfaces of adjacent endplates of vertebrae between which the implant is inserted.

7. A spinal disc implant in accordance with claim **5**, wherein the implant includes a hole formed in the ring-shaped body, and further comprising a screw inserted in the hole for fixing the hydroxyapatite block in the central bore of the implant.

8. A spinal disc implant in accordance with claim **3** wherein the upper and lower surfaces of the ring-shaped body are curved to mate with adjacent endplates of vertebrae between which the implant is inserted.

9. A spinal disc implant having a generally elongated D-shaped body, the body tapering in thickness from a first end to a second end along first and second faces thereof, a degree of taper and thickness to allow the implant to fit within a cavity created by removal of a diseased or damaged vertebral disc and defined by an angle formed by adjacent vertebral bodies from between which the vertebral disc is removed, said spinal disc implant being of titanium or an alloy thereof and having a central bore open to first and second faces thereof being filled by a porous hydroxyapatite block shaped to substantially fill the central bore, the spinal disc implant additionally having a plurality of teeth projecting along the perimeter of the D-shaped body on the first and second faces for engaging bony and soft tissue of adjacent vertebrae, the teeth encircling the hydroxyapatite block and the second face convexly curved to mate with an overlying or underlying surface of a vertebral body on which the implant rests.

* * * * *

US006231610B1

(12) **United States Patent**
Geisler

(10) **Patent No.: US 6,231,610 B1**
(45) **Date of Patent: May 15, 2001**

(54) **ANTERIOR CERVICAL COLUMN SUPPORT DEVICE**

(75) Inventor: **Fred Geisler**, Evanston, IL (US)

(73) Assignee: **Allegiance Corporation**, McGaw Park, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/382,808**

(22) Filed: **Aug. 25, 1999**

(51) **Int. Cl.**[7] **A61F 2/44**
(52) **U.S. Cl.** **623/17.11**
(58) **Field of Search** 623/17.11, 17.16; 606/61

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6,066,175	*	5/2000	Henderson et al. 623/17.11

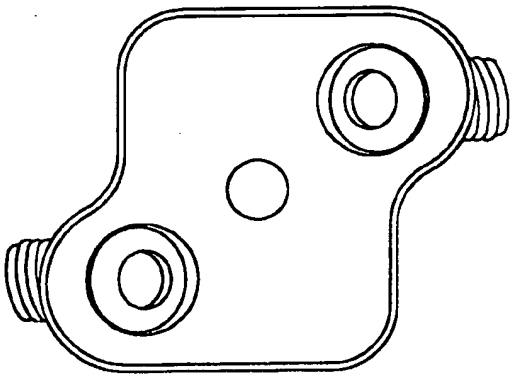
* cited by examiner

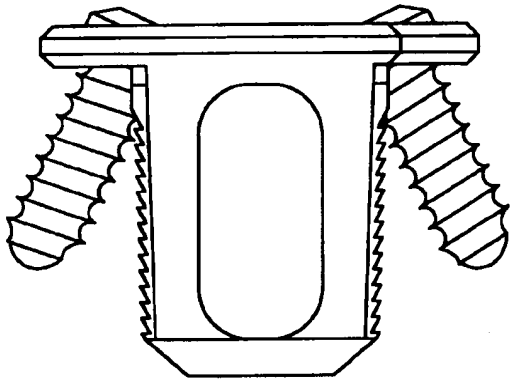
Primary Examiner—Jeffrey A. Smith
(74) *Attorney, Agent, or Firm*—Donald O. Nickey; Andrew G. Rozycki

(57) **ABSTRACT**

An spinal column support device for stabilizing and repairing problems associated with the material located between vertebra located in the cervical area of the spinal column. The support device has a hollow isosceles trapezoidal right prism-shaped skeletal frame with two load bearing surfaces. Each load bearing surface includes serrations. The support device also includes a cervical plate having two screw holes. The support devices is inserted between two vertebrae located in the cervical area of the spine wherein each vertebrae rests on a load bearing surface. The serrations keep the support device from backing out, while screws in the screw holes of the cervical plate help hold the cervical plate in position.

7 Claims, 2 Drawing Sheets





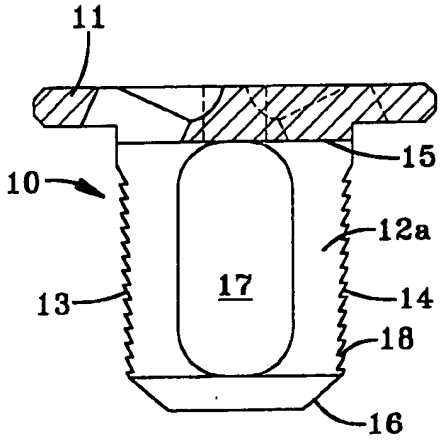


FIG-1

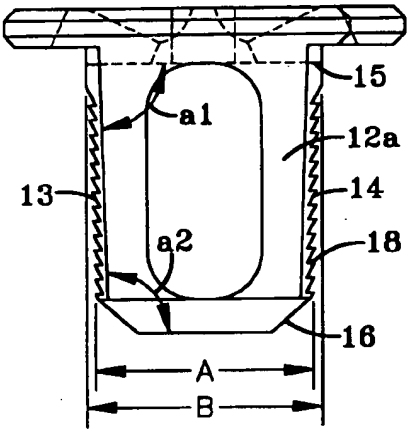


FIG-2

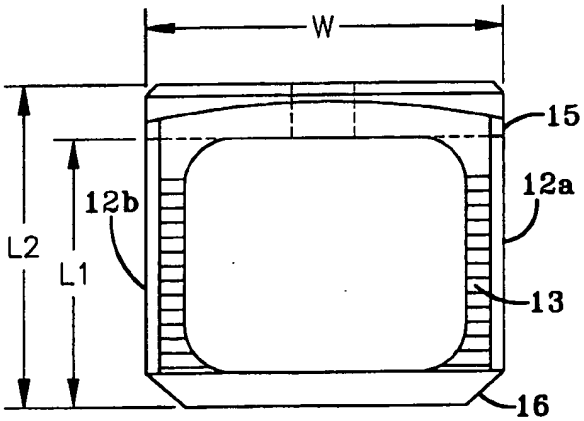


FIG-3

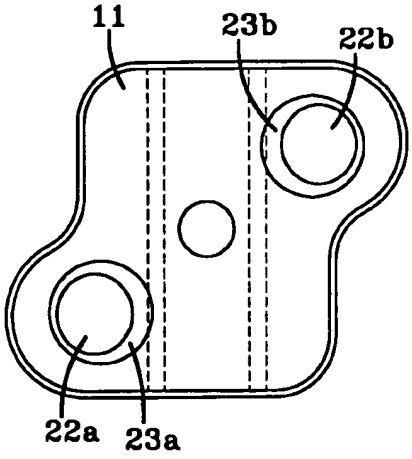
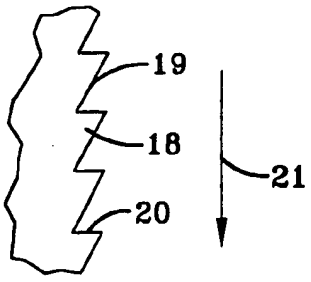


FIG-4

FIG-5



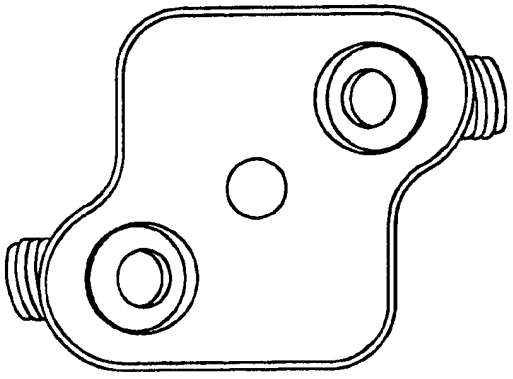


FIG-6

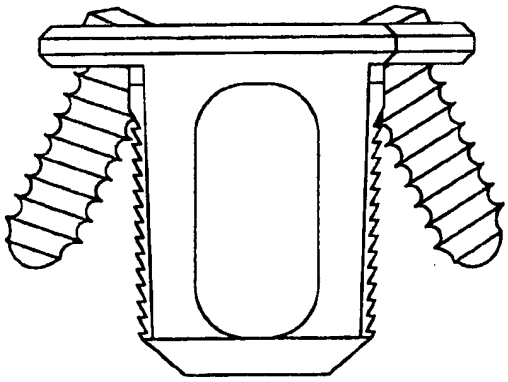


FIG-7

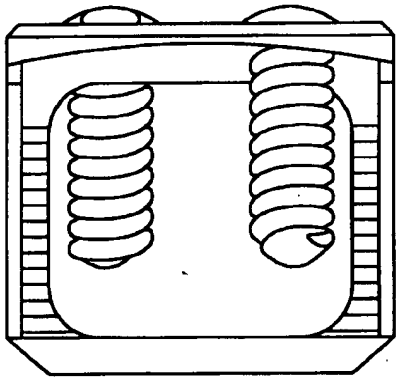


FIG-8

ANTERIOR CERVICAL COLUMN SUPPORT DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to spinal column spacers and specifically to an anterior cervical column support device.

2. Description of the Prior Art

Several prior art spacers exist for repairing the spinal column. However, most spacers are designed for the lumbar or thoracic regions of the spine whereas most devices for repairing the cervical area of the spine usually involves some type of screw and rod system. The following U.S. Patents are examples.

U.S. Pat. No. 5,397,363 issued to Gelbard on Mar. 14, 1995 shows a spinal stabilization implant system. It uses plates and screws to stabilize the vertebrae of the cervical area. "The instant invention is a surgical implant system for the stabilization of the human spine by fixation of the vertebra. The system is based upon screws, nuts, rods, hooks, cross-members and variations thereof. The preferred embodiment employs a metal screw for placement in the sacrum or pedicle defined by a coarse self-tapping thread and a U-shaped saddle for placement of conventional alignment rods. Unique to this invention is that the screw is threaded on the outer surface of the saddle allowing the alignment rod to be securely fastened into the saddle by placement of the rod therein and the fastening of a nut to the top of the saddle. Further unique to this invention is the use of an elongated sagittal traverse support member that can accommodate the saddle protrusion either in a fixed position or by use of a rotatable insert that allows the cross member to be tightly fastened to the saddle in a variable alignment. The top-loading attachment is further applicable to caudal, cranial, and the like hook components. An anterior cervical plate is set forth using a second plate to permanently lock the cervical plate in position. The second plate does not rely upon the bone to support the place thus providing means to prevent any bone attachment screws from loosening or otherwise backing out of the bone."

U.S. Pat. No. 5,507,745 issued to Logroscrino et al. on Apr. 16, 1996 shows an occipito-cervical osteosynthesis instrumentation. It is another example of a rod-type system used on the cervical area of the spine. It comprises "two separate similar parts, namely a right and a left part, each formed by a cervical rod having asperities and an elongate occipital plate which forms one piece with said rod and extends said rod toward the occiput in the position of use, [an] adjustable means for anchoring the rod to the vertebrae and the plate to the occiput, each part being so preangulated and shaped as to be adapted to the anatomy of the occipito-cervical connection." This patent also recognizes that the cervical area of the spine requires a specific curvature for proper healing.

U.S. Pat. No. 5,713,900 issued to Benzel et al. on Feb. 3, 1998 shows an apparatus for retaining bone portions in a desired spatial relationship. The abstract states that it is "[a] apparatus for retaining first and second bone portions in a desired spatial relationship compris[ing] a first member positionable along the first and second bone portions. A second member connectable with the first bone portion has surface member defining an opening. A fastener is extendable through the opening in the second member to connect the second member to the first bone portion. The fastener has a first portion for engaging the first bone portion and a second portion for clamping the first member against the second member to fix the first and second members against relative movement. The first member is also connected to the second bone portion."

Very few references disclose the use of implantable spacers as a solution to cervical vertebra stabilization. Those that do, lack the advantages of the present invention.

The human spinal column consists of 33 (sometimes 34) vertebrae divided into five groups: cervical, thoracic, lumbar, sacral and coccygeal vertebrae areas. The sacral vertebrae are fused into a single bone as is the coccygeal vertebrae, usually designated as the coccyx. The movable vertebrae are found in the cervical, thoracic and lumbar areas. Each area has a characteristic curve. Various vertebrae differ in size and shape depending on the location in the spinal column. This means that a spacer designed for the lumbar or thoracic region will not perform properly in the cervical region. The present invention solves the problem of stabilization of the cervical vertebrae by providing a properly designed spacer for the cervical area.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an implantable spacer which performs as an anterior cervical column support device.

The instant invention is an anterior cervical spinal column support. It consists of a hollow isosceles trapezoidal right prism-shaped skeletal frame designed to fit between and stabilize cervical vertebrae. It provides spacing and support where, for example, the intevertebral disc has failed due to a slipped, herniated or ruptured disc. Specifically, it is used in one or two level anterior cervical discectomy in degenerative disc disease where. fusion and internal stabilization is desired. It also corrects and provides better support for the lateral bending and lordosis angles. It includes bottom and top load bearing surfaces. Each surface lies in a plane which makes a 1–5 (preferably 1–2) degree angle with the horizon so as to provide the proper angle for the cervical vertebrae. These surfaces bear the weight and forces on the vertebrae and are held in place primarily by frictional forces between the vertebrae and the serrated portions on the top and bottom load bearing surfaces. The support also includes a plate attached to the back portion and including screw holes allowing the plate to be connect to the vertebrae by screws. These screws do not provide primary support and are not load bearing. Their function is to hold the plate in position. The support is constructed of any bio-compatible material, such as titanium. The hollow space within the support is designed to hold a bone graft, or any other type of bone grafting material.

It is an object of the present invention to provide an inter-discal spacer and support for the vertebrae of the cervical area of the spine.

It is an object of the present invention to provide a cervical inter-discal support which includes a hollow portion for receiving bone grafting material.

It is an object of the present invention to provide an anterior cervical column support device which restores and/or maintains the correct lordodic balance better than prior art rod and screw devices.

It is an object of the present invention to provide an anterior cervical column support device which properly restores saggital balance.

These together with other objects of the invention, along with various features of novelty which characterize the invention, are pointed out with particularity in the claims

annexed to and forming part of this disclosure. For a better understanding of the invention, its operating advantages and the specific objects attained by its uses, reference should be made to the accompanying drawings and descriptive matter in which there is illustrated preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood and objects other than those set forth above will become apparent when consideration is given to the following detailed description thereof. Such description makes reference to the annexed drawings wherein:

FIG. 1 is a side view of the anterior cervical column support device.

FIG. 2 is a side view of the anterior cervical column support device showing details of the angles between the top load bearing surface and the bottom load bearing surface.

FIG. 3 is a top view of the anterior cervical column support device showing the serrations on the top load bearing surface of the support device.

FIG. 4 is a rear view of the anterior cervical column support device showing the rear plate and associated screw holes.

FIG. 5 is a detailed side view of top load bearing surface showing the serrations.

FIG. 6 is a rear view of the anterior cervical column support device showing the rear plate with the associated screws.

FIG. 7 is a side view of the anterior cervical column support device with the associated screws.

FIG. 8 is a top view of the anterior cervical column support device with the associated screws.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The anterior cervical column support device **10** is a hollow isosceles trapezoidal right prism-shaped skeletal frame comprising a rear plate **11**, two trapezoidal shaped side surfaces **12***a* and **12***b*, a rectangular shaped top load bearing surface **13**, a rectangular shaped bottom load bearing surface **14**, a back surface **15** and a front surface **16**. The rear plate **11** is attached to the back surface **15** of the support device **10**. The rear plate **11** also includes two screw holes for attaching the plate to the two adjacent vertebral bodies on either side of the support device **10** once the support device **10** is in place. The width "W" of the back surface **15** and the front surface **16** are equal. The height "A" of the front surface **16**, however, is shorter than the height "B" of the back surface **15**. This configuration forms the isosceles trapezoidal shape. The top load bearing surface **13**, bottom load bearing surface **14** and the two side surfaces **12***a* and **12***b* are skeletal in configuration. Each of these surfaces provide access to the interior **17** of the support device **10**. The interior **17** of the support device **10** receives cartilage or any other bone grafting material. This allows the vertebrae on each side of the support device **10** to fuse together using the cartilage material.

As shown in FIG. **1**, the side view of the anterior cervical column support device **10** shows the rear plate **11** attached to the back surface **15** of the support device **10**. It also shows a side surface **12***a*. Each side surface **12***a* and **12***b* has the same shape and size. FIG. **1** also shows a side view of the top load bearing surface **13** and the bottom load bearing surface **14**. These surfaces **13** and **14** have the same size and shape and are named differently for the purpose of description only. Each surface **13** and **14** includes serrations **18**.

FIG. **2** shows a detailed side view of the anterior cervical column support device **10**. It shows the height "B" of the rear surface **15** and the height "A" of the front surface **16**. The side surfaces **12***a* and **12***b* have a trapezoidal shape which can clearly be seen from FIG. **2**. The back end of the trapezoid has a height "B" and the front end of the trapezoid has a height "A." Height "A" and height "B" are designed for specific areas within the cervical region of the spine and specifically are designed to fit between certain vertebrae in that area. The heights "A" and "B" provide the proper spacing between the vertebra while the difference between the heights "A" and "B" create an angle a1 between the rear surface **15** and the top load bearing surface **13** and an angle a2 between the front surface **16** and the top load bearing surface **13**. Angle a1 can be between 85 and 89 degrees whereas the corresponding angle a2 is between 91 and 95 degrees. In the preferred embodiment, angle a1 is between 88 and 89 degrees whereas angle a2 is between 91 and 92 degrees. Angles a1 and a2 are also present with respect to the bottom load bearing surface **14** as it is attached to the rear surface **15** and the front surface **16**. The angles a1 and a2, the top load bearing surface **13** and the bottom load bearing surface **14** form a trapezoidal shape which holds the vertebrae in the proper position. In this manner, the support device **10** holds the proper lordodic balance and restores the sagittal balance between the vertebrae in the cervical area of the spine.

FIG. **3** shows a top view of the anterior cervical support device **10**. The serrations **18** on the top load bearing surface **13** are clearly visible as is the rectangular shape of the top load bearing surface **13**. The width "W" of the top load bearing surface **13**, the bottom load bearing surface **14**, the rear surface **15** and the front surface **16** are all equal. In the preferred embodiment, the width is 12 to 15 millimeters. However, this width can vary according to the size of the vertebrae of the cervical area of the spine of the particular patient.

FIG. **4** shows a detailed view of the rear plate **11**. The rear plate **11** is primarily a cervical plate used in the prior art. The rear plate **11** is attached to the rear surface **15** of the anterior cervical column support device **10**. The rear plate **11** includes two screw holes **22***a* and **22***b*. These screw holes **22***a* and **22***b* include angled indentations **23***a* and **23***b* which make one screw go into the vertebra supported by the top load bearing surface **13** and the other screw go into the vertebra supported by the bottom load bearing surface **14**. The screws (not shown in the drawings) can be made of any bio-compatible material. Preferably, the screws are titanium uni-cortical screws having a 14 millimeter length. These screws are used to hold the rear plate **11** in position.

All components of the anterior cervical column support device are made of biocompatible material. Preferably the material is titanium, 6AL-4V ELI alloy.

A detailed view of these serrations **18** can be seen in FIG. **5**. Arrow **21** in FIG. **5** indicates the direction of insertion of the support device **10**. With respect to the direction of insertion, the serrations **18** include a sloping front side **19** and a perpendicular **20** rear side. This allows for easy movement in one direction and difficult movement in the other direction. These serrations **18** provide the primary frictional support for the support device **10**.

It will be apparent to those skilled in the art that various modifications and variations can be made to the anterior cervical spinal column support device. Thus, it is intended

that the present invention cover such modifications and variations, provided they come within the scope of the appended claims and their equivalents. The disclosure of all publications cited above are expressly incorporated herein by reference in their entireties to the same extent as if each were incorporated by reference individually.

I claim:

1. A anterior cervical column support device for insertion between a first spinal vertebra and a second spinal vertebra, comprising:

a hollow isosceles trapezoidal right prism-shaped skeletal frame having a front surface, a rear surface, two side surfaces, a top load bearing surface and a bottom load bearing surface;

each side surface has a trapezoidal shape and attached between the front surface and rear surface;

the top load bearing surface attaches to each side surface and to the front and rear surfaces such that an obtuse angle is formed between the top load bearing surface and the front surface and an acute angle is formed between the top load bearing surface and the rear surface, wherein the top load bearing surface includes serrations for increasing frictional forces between the top load bearing surface and the first vertebrae; and

the bottom load bearing surface attaches to each side surface and to the front and rear surfaces such that an obtuse angle is formed between the bottom load bearing surface and the front surface and an acute angle is formed between the bottom load bearing surface and the rear surface, wherein the bottom load bearing surface includes serrations for increasing frictional forces between the bottom load bearing surface and the second vertebrae; and

a rear plate attached to the rear surface of the support device, the rear plate including two indented offset screw holes for receiving two screws for holding the rear plate in position.

2. The anterior cervical column support device of claim 1 wherein the acute angle between the top load bearing surface and the rear surface and the acute angle between the bottom load bearing surface and the rear surface is between 85 and 89 degrees and the corresponding obtuse angle between the top load bearing surface and the front surface and the obtuse angle between the bottom load bearing surface and the front surface is between 91 and 95 degrees.

3. The anterior cervical column support device of claim 2 wherein the acute angle between the top load bearing surface and the rear surface and the acute angle between the bottom load bearing surface and the rear surface is between 88 and 89 degrees and the corresponding obtuse angle between the top load bearing surface and the front surface and the obtuse angle between the bottom load bearing surface and the front surface is between 91 and 92 degrees.

4. The anterior cervical column support device of claim 1 wherein one screw is driven into the first vertebrae and one screw is driven into the second vertebrae.

5. The anterior cervical column support device of claim 1 wherein the entire support device is constructed of bio-compatible material.

6. The anterior cervical column support device of claim 5 wherein the bio-compatible material is titanium.

7. The anterior cervical column support device of claim 1 wherein the serrations on the top load bearing surface and the serrations on the bottom load bearing surface are uni-directional.

* * * * *

US006245108B1

(12) **United States Patent**
Biscup

(10) **Patent No.: US 6,245,108 B1**
(45) **Date of Patent: Jun. 12, 2001**

(54) **SPINAL FUSION IMPLANT**

(75) Inventor: **Robert S. Biscup**, Vermilion, OH (US)

(73) Assignee: **Spineco**, Westlake, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/494,645**

(22) Filed: **Jan. 31, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/121,705, filed on Feb. 25, 1999.

(51) **Int. Cl.**[7] **A61F 2/44**

(52) **U.S. Cl.** **623/17.11**; 623/17.16; 606/61

(58) **Field of Search** 623/17.16, 17.11, 623/16.11; 606/60, 61, 53

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Primary Examiner—Pedro Philogene
(74) *Attorney, Agent, or Firm*—Vickers, Daniels & Young

(57) **ABSTRACT**

An improved prosthetic implant for forming a rigid structure between adjoining vertebrae in a spinal column. The prosthetic implant includes a cage having a top, bottom, front end, back end, first side and second side walls. The first side wall has an arcuate surface. The top and bottom wall include one or more ridges to engage a surface of an adjacent vertebrae. The top and bottom walls also include an opening to receive packing material such as medicine, human tissue and the like. The top and bottom walls also incline simultaneously in two directions.

59 Claims, 4 Drawing Sheets

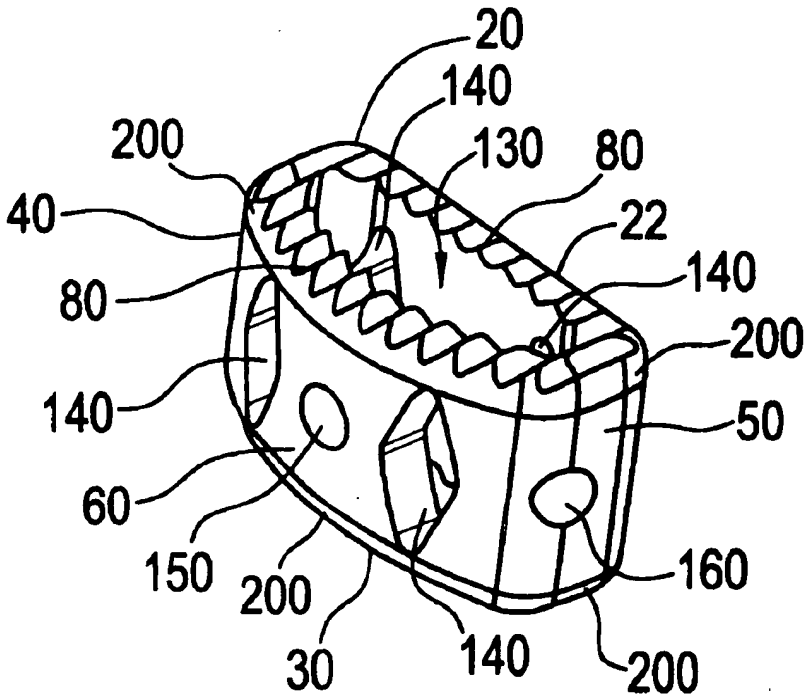
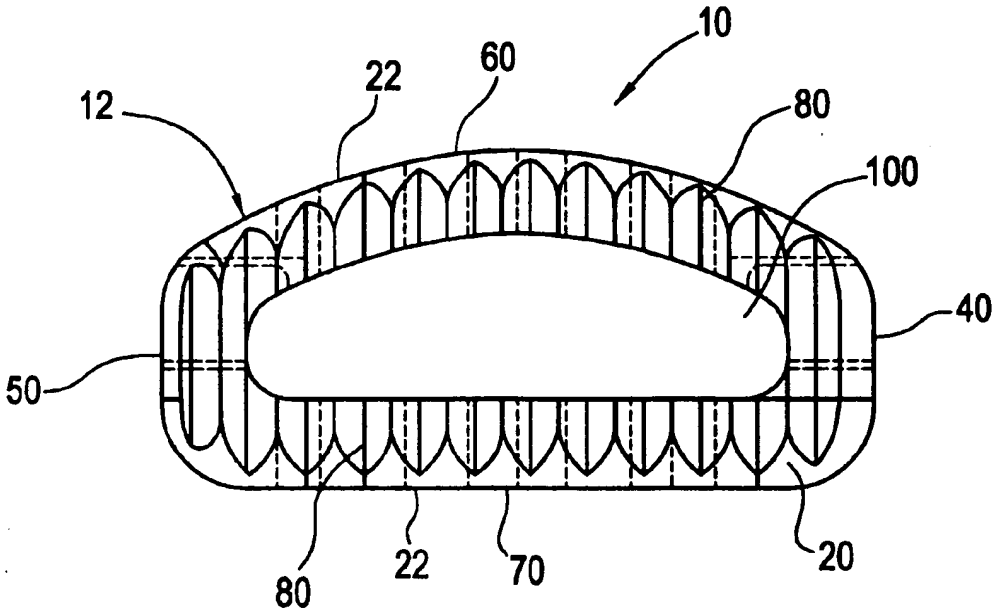


FIG. 1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100
40
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80
22
70
20

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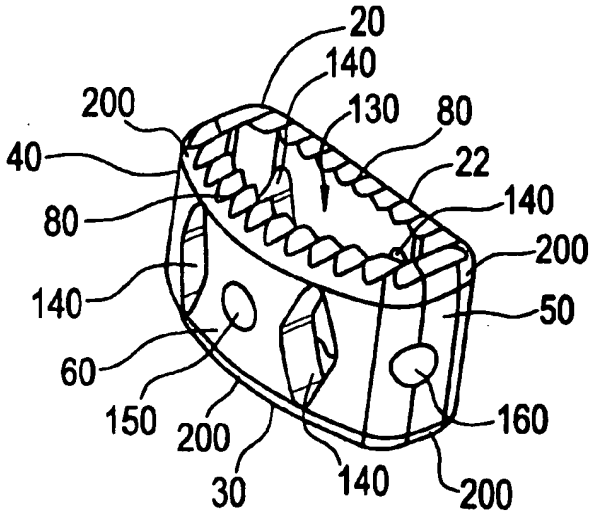
20
140
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22
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140
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160
30
140
200

FIG. 3

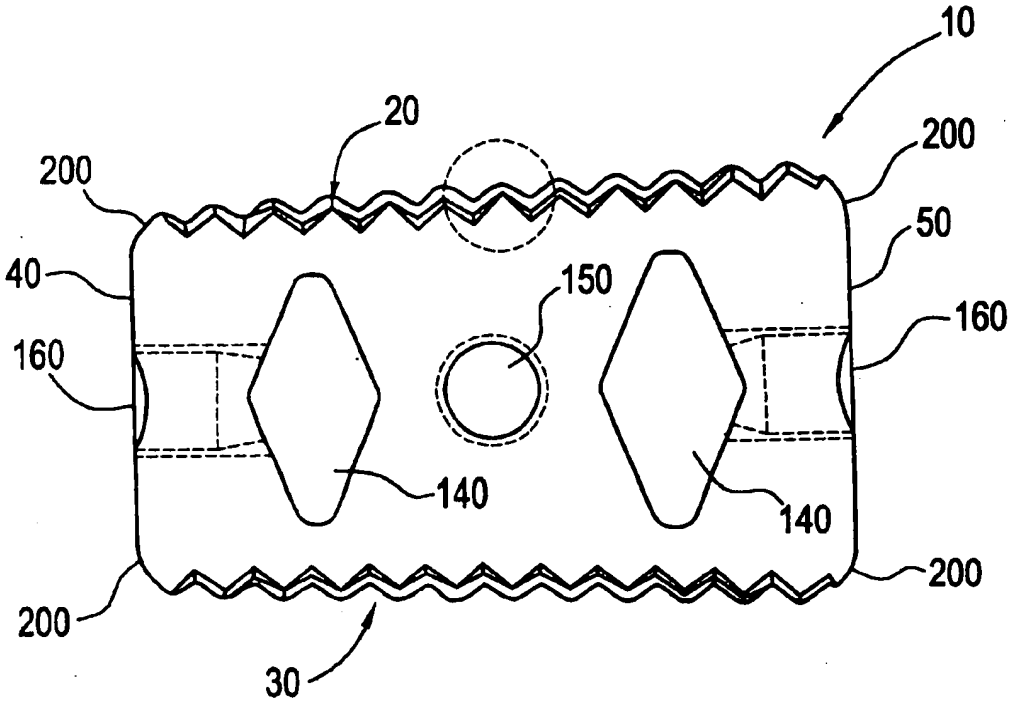


FIG. 3A

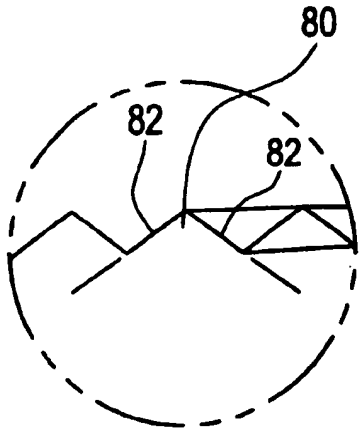


FIG. 4

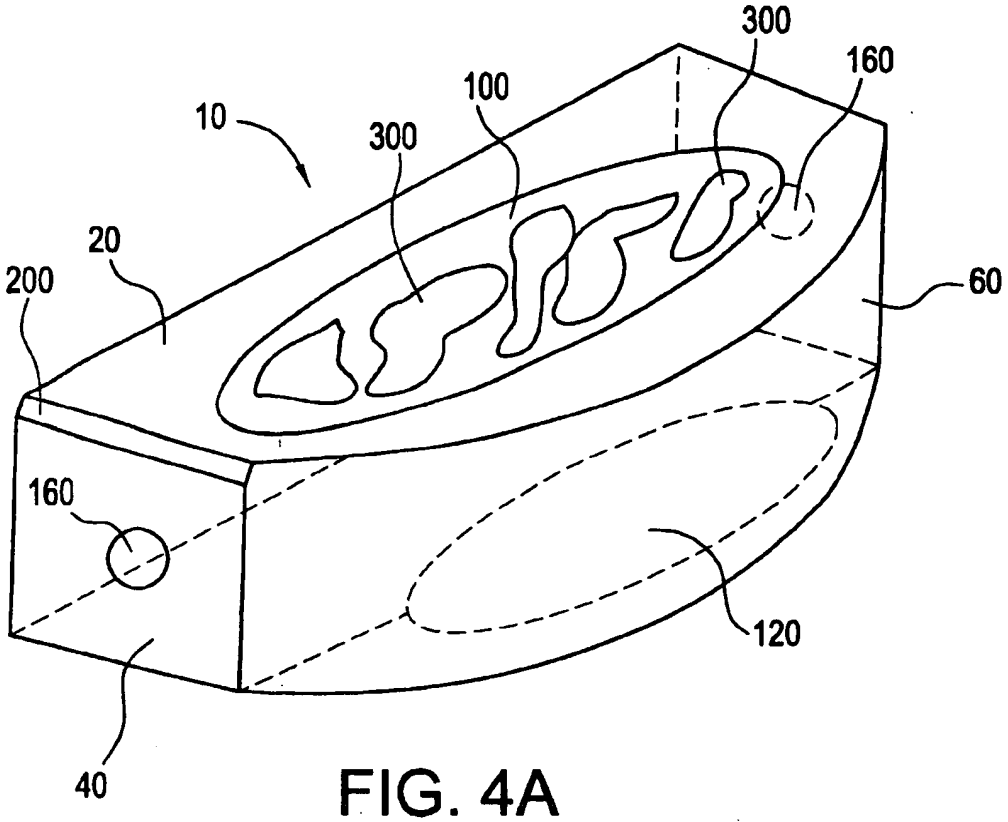


FIG. 4A

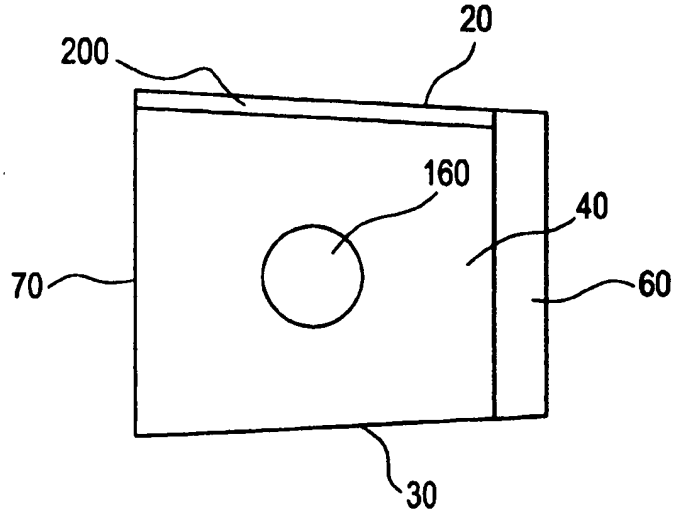


FIG. 5

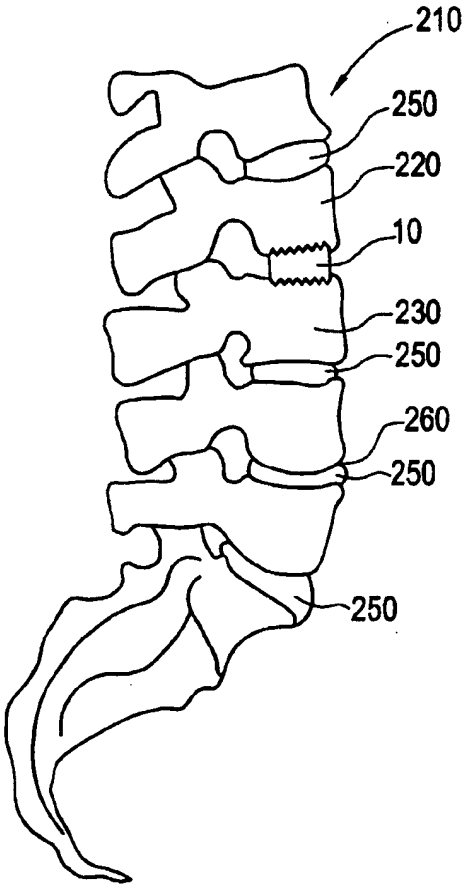
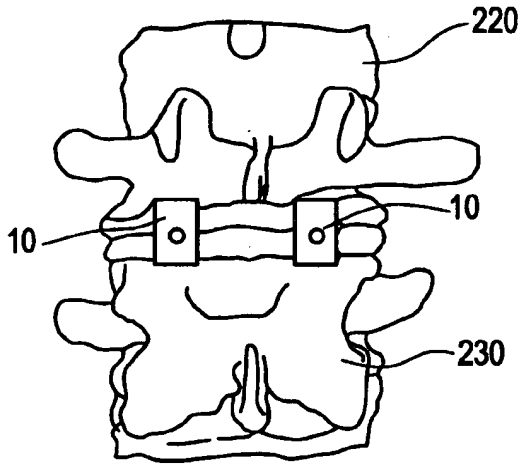


FIG. 6



SPINAL FUSION IMPLANT

This application claims priority on my co-pending U.S. Provisional Application Ser. No. 60/121,705, filed Feb. 25, 1999 entitled "Spinal Fusion Implant."

The present invention pertains to prosthetic implants and more particularly to inner body spinal prosthetic implants to fuse two or more vertebrae together.

INCORPORATION BY REFERENCE

U.S. Provisional Application Ser. No. 60/121,705, filed Feb. 25, 1999 entitled "Spinal Fusion Implant" is incorporated by reference.

BACKGROUND OF THE INVENTION

The human spine is made up of a column of thirty-three bones and their adjoining structures. The vertebrae near the head are known as the presaccral vertebrae which are separate bones capable of individual movement. The bodies of these vertebrae are connected by anterior and posterior ligaments and by disks of fibrocartilage generally known as intervertebral disks. These disks are positioned between opposite faces of adjacent vertebral bodies. This column of vertebrae and intervertebral disks form a central axis that supports the head and torso. These vertebrae also enclose an opening through which the spinal cord passes therebetween.

The presaccral vertebrae are normally held in position to one another by the intervertebral disks, ligaments and musculature of the body. These vertebrae move relative to adjacent vertebrae thus permitting the head to be turned relative the body and providing a wide range of flexibility to the spine.

One of the most costly health problems to society involves back pain and pathology of the spine. These problems can affect individuals of all ages and can result in great suffering to victims. Back pain can be caused by several factors such as congenital deformities, traumatic injuries, degenerative changes to the spine and the like. Such changes can cause painful excessive motion, or collapse of a motion segment resulting in the contraction of the spinal canal and compresses the neural structures causing debilitating pain, paralysis or both which in turn can result in nerve root compression or spinal stenosis.

Nerve conduction disorders can also be associated with invertible disks or the vertebrae themselves. One such condition is herniation of the intervertebral disk, in which a small amount of tissue protrudes from the sides of the disk into the foramen to compress the spinal cord. A second common condition involves the development of small bone spurs, termed osteophytes, along the posterior surface of the vertebral body, again impinging on the spinal cord.

Upon identification of these abnormalities, surgery may be required to correct the problem. For those problems associated with the formation of osteophytes or herniations of the intervertebral disk, one such surgical procedure is intervertebral diskectomy. In this procedure, the involved vertebrae are exposed and the intervertebral disk is removed, thus removing the offending tissue, or providing access for the removal of the bone osteophytes. A second procedure, termed a spinal fusion, may then be required to fix the vertebrae together to prevent movement and maintain a space originally occupied by the intervertebral disk. Although this procedure may result in some minor loss and flexibility in the spine, due to the relatively large number of vertebrae, the minor loss of mobility is typically acceptable.

During a spinal fusion following a diskectomy, a prosthetic implant or spinal implant is inserted into the intervertebral space. This prosthetic implant is often a bone graft removed from another portion of the patient's body, termed an autograph. The use of bone taken from the patient's body has the important advantage of avoiding rejection of the implant, but has several shortcomings. There is always a risk in opening a second surgical site in obtaining the implant, which can lead to infection or pain for the patient, and the site of the implant is weakened by the removal of bony material. The bone implant may not be perfectly shaped and placed, leading to slippage or absorption of the implant, or failure of the implant to fuse with the vertebrae.

Other options for a graft source of the implant are bone removed from cadavers, termed allograft, or from other species, termed a xenograft. In these cases while there is the benefit of not having a second surgical site as a possible source of infection or pain, there is increased difficulty of the graft rejection and the risk of transmitting communicable diseases.

An alternative approach is using a bone graft or to use a manufactured implant made of a synthetic material that is biologically compatible with the body and the vertebrae. Several compositions and geometries of such implants have been utilized, ranging from simple blocks of material to carefully shaped implants, with varying success.

There has been an extensive number of attempts in developing an acceptable prosthetic implant that can be used to replace an intervertebral disk and yet maintain the stability of the intervertebral disk spaced between adjacent vertebrae, at least until complete arthrodesis is achieved. These prosthetic implants have taken many forms. While many types of synthetic prosthetic devices have been proposed, the success ratio has been low and the surgical procedures have been complicated and often traumatic to the patient.

One of the more prevailing designs of these prosthetic implants takes form of a cylindrical implant. These types of prosthetic implants are represented by Brantigan U.S. Pat. No. 4,878,915 and Ray U.S. Pat. No. 4,961,740. In these cylindrical implants, the exterior portion of the cylinder can be threaded to facilitate insertion of the prosthetic device. Some of these prosthetic implants are designed to be pounded into the intervertebral disk space and the vertebral end plates. These types of devices are represented in Brantigan U.S. Pat. No. 4,834,757 and Brantigan U.S. Pat. No. 5,192,327. The Brantigan and Ray patents all disclose prosthetic implants wherein the transverse cross-section of the implant is constant throughout the length of the implant and is typically in the form of a right circular cylinder.

Other prosthetic implants have been developed that do not have a constant cross-section. For instance, the patent to McKinna U.S. Pat. No. 4,714,469 shows a hemispherical implant with elongated protuberances that project into the vertebral end plate. The implant of Bagby U.S. Pat. No. 4,934,848 is in the form of a sphere which is positioned between the centrums of the adjacent vertebrae.

The various prosthetic implants can be generally divided into two basic categories, namely, solid implants and implants that are designed to encourage bone ingrowth. Solid implants are represented by U.S. Pat. Nos. 4,878,915 and 4,349,921. The remaining patents discussed above include some aspect that permits bone to grow across the implant. It has been found that devices which promote natural bone ingrowth achieve a more rapid and stable arthrodesis. These implants are typically filled with autologous bone prior to insertion into the intervertebral disk space. These implants typically include apertures which

communicate with openings in the implant, thereby providing a path for tissue growth between the vertebral end plate and the bone or bone substitute within the implant. In preparing the intervertebral disk space for a prosthetic implant, the end plates of the vertebrae are preferably reduced to bleeding bone to facilitate tissue growth within the implant.

A number of difficulties still remain with the many prosthetic implants currently available. While it is recognized that hollow implants which permit bone ingrowth in the bone or bone substitute within the implant is an optimum technique for achieving fusion, most of these devices have difficulty achieving this fusion, at least without the aid of some additional stabilizing device, such as a rod or plate. Moreover, some of these devices are not structurally strong enough to support the heavy loads applied at the most frequently fused vertebral levels, mainly those in the lower lumbar spine.

There has been a need for providing a prosthetic implant that optimizes the bone ingrowth capabilities and strong enough to support the vertebrae until arthrodesis occurs. There is a further need for such an implant that is capable of maintaining or restoring the normal spinal anatomy at the instrumented segment. There is also a need for an implant that exhibits reduced slippage when inserted between vertebrae and diminishes the occurrence of nerve pinching.

SUMMARY OF THE INVENTION

The present invention pertains to an improved implant and more particularly to an improved prosthetic implant used to facilitate in the fusion of two or more vertebrae.

In accordance with the principal feature of the present invention, there is provided a prosthetic implant that is formed of a biologically compatible material for use in humans. The prosthetic implant is shaped and sized for insertion between two vertebrae. In one specific embodiment, the prosthetic implant is designed to be placed in the intervertebral disk space that was formerly occupied by an intervertebral disk. The intervertebral disk is partially or completely removed prior to insertion of the prosthetic implant between the vertebrae. In one specific embodiment, the shape and size of the cage is selected to have an anatomically correct shape. In another embodiment, the prosthetic implant is shaped to increase the area of contact with the vertebrae and/or to closely emulate the region formerly occupied by the intervertebral disk. In still another embodiment, the prosthetic implant is designed to be readily inserted by established surgical procedures, with minimal chances of surgical difficulty. In yet another embodiment, the geometry of the implant ensures proper load bearing, desired load bearing and support through the fused vertebrae minimizing the likelihood of the prosthetic implant dislocating relative to the vertebrae either during surgery or during the post operative fusing process.

In accordance with another aspect of the present invention, there is provided a prosthetic implant which includes a cage having a top wall, a bottom wall, a front end wall, a back end wall, a first side wall, and a second side wall. In one embodiment, the cage is made of a material that is inert or biologically compatible with the vertebrae. The material of the cage includes, but is not limited to, bone, stainless steal, titanium, chrome, cobalt, polycarbonate, polypropelene, polyethylene, polymethylmethacrylate, polysolfone types filled with glass and/or carbon fibers, and various types of carbon and fiber reinforced polymers. In accordance with another embodiment, the cage is designed to maintain a tension load of about ten to forty pounds and more preferably about fifteen to thirty-five pounds on the disk tissue. This tension load facilitates in maintaining the cage in position between the vertebrae and accelerates bone ingrowth between the vertebrae. In still another embodiment, the cage is made of a material which closely approximates the elasticity of the vertebra. In still yet another embodiment, the cage is coated with and/or made up of material which is radiolucent to enhance the visibility of the implant when exposed to X-rays.

In accordance with still another aspect of the present invention, the first side wall and second side wall of the cage of the prosthetic implant extends substantially along the longitudinal axis of the cage and wherein the two side walls are configured to enhance the stability of the cage within the intervertebral disk space. In one embodiment, the first and/or second side wall is at least partially arcuate. In another embodiment, the first and second side wall have different face configurations. In one specific embodiment, the first side includes an arcuate surface and the second side has a substantially flat or planar surface. In one specific embodiment, the first side wall has a substantially uniform arcuate surface. In another specific embodiment, the actuate surface has a radius of curvature of about 2 to 30 degrees. In cage configurations having an arcuate first side wall surface, the cage is positioned in the intervertebral disk space such that the substantially flat or planar surface of the second side is positioned closely adjacent to the spinal cord and the first side is positioned adjacent the peripheral edge of the intervertebral disk space. Prosthetic implant cages having an arcuate or curvilinear side wall have been found to more closely conform to the surfaces with the intervertebral disk space thereby resulting in a higher degree of success for fusing together two vertebrae. The different side configurations of the cage also function as a visual aid to ensure that the cage is properly oriented between two vertebrae.

In accordance with yet another aspect of the present invention, the cage of the prosthetic implant includes a top wall and/or bottom wall having at least one rigid surface adapted to engage the underside surface of a vertebrae within the intervertebral disk space. The ridge is designed to secure or bite into the vertebrae surface. In one embodiment, the top wall includes a plurality of ridged surfaces. In another embodiment, the bottom wall includes a plurality of ridged surfaces. The ridged surfaces on the top and/or bottom wall can have a number of configurations. In one specific embodiment, the ridges have diamond shaped surfaces, thereby functioning similar to teeth-like structures. In another specific embodiment, the ridge is a uniform structure extending over the lateral and/or longitudinal surface of the top and/or bottom wall. In another embodiment, the ridges are positioned on the top end and/or bottom wall and are spaced from the outer peripheral edge of the bottom and/or top wall. In still another embodiment, the top and bottom wall have similar ridge configurations and a similar number of ridges; however, it can be appreciated that the top and bottom wall can have different numbers and/or different configurations of ridges. In still yet another embodiment, the ridges in the top and/or bottom wall of the cage anchor the cage in between the vertebrae and provide channels for bone ingrowth which facilitates in the fusion of the vertebrae.

In accordance with still yet another aspect of the present invention, the cage of the prosthetic implant includes one or more openings in one or more of the walls of the cage. In one embodiment, the openings are designed to receive materials which facilitate in the fusion of the vertebrae, facilitate in the

positioning of the cage between the vertebrae, and/or secure the cage in place within the intervertebral disk space. In one specific embodiment, one or more of the openings are designed to receive a packing material which facilitates in the formation of a graft between two vertebrae. Such packing material can include, but is not limited to, medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and the like. In another specific embodiment, the cage includes a plurality of openings to allow blood supply to grow from the sides of the cage to the vertebrae between the cage. In still another specific embodiment, one or more openings in the cage are filled with a packing material which includes one or more components that are selected to grow out of the openings of the cage radially, longitudinally and/or vertically from the cage and grow into the bone tissue of the adjoining adjacent vertebrae. In still another specific embodiment, one or more openings are filled with bone material or a synthetic material, with or without a bone activating matter such as hydroxyapatite bone or phallic protein, bone growth factor, or cartilage activation factor. In yet another embodiment, the top and/or bottom wall of the cage have an opening which communicates with an internal cavity of the cage. In still yet another embodiment, the top and bottom walls include at least one opening that are substantially the same shape and size. In accordance with another embodiment, the first side wall, second side wall, front end wall and/or back end wall include at least one opening adapted to receive an instrument for guiding and/or inserting the cage between the vertebrae of the spine by an anterior, posterior, lateral and/or latroscopic approach into the spinal column. The openings allow a surgeon to select which approach is best for inserting the prosthetic implant in the intervertebral disk space. In one specific embodiment, the instrument opening includes a securing mechanism, such as, but not limited to, a thread, in the opening to secure the instrument within the opening.

In accordance with another aspect of the present invention, at least one or more edges of the cage are rounded off so as not to be sharp. The rounding off of the edges reduces and/or eliminates pinching of the nerve leading from the spinal cord which can result in pain, damage or paralysis to the individual. The rounded edges avoid or minimize nerve pressure that can be exerted on the nerves intervertebrally exiting the spinal cord. The one or more rounded off edges also facilitates with the insertion of the cage within the intervertebral disk space. In one specific embodiment, the lateral edges of the cage are rounded off. In another specific embodiment, all the edges of the cage are rounded off.

In accordance with still another aspect of the present invention, the top wall and/or bottom wall are at least partially inclined along the longitudinal axis of the cage. In one embodiment, the top wall and/or bottom wall are uniformly inclined from the back end wall to the front end wall. In one specific embodiment, the back end wall is higher than the front end wall. In another specific embodiment, the angle of inclination of the top and/or bottom wall is about 0.5 to 15 degrees and preferably about 1 to 10 degrees and more preferably about 3 to 8 degrees. The inclination of the top and/or bottom wall of the cage facilitates in the ease of insertion into the vertebrae column and/or provides a better fit for the cage within the intervertebral disk space since the inclination better matches the anatomical shape of the space between the vertebrae of the spinal column. In accordance with another embodiment, the inclined top and/or bottom wall of the cage accommodate the positioning of the cage between two vertebrae of the spinal column and the ridges on the top and/or bottom wall of the cage are adapted to contact the surfaces of the vertebrae bone and secure the cage in position between the vertebrae until the fusion of the vertebrae is complete.

In accordance with yet another aspect of the present invention, the top wall and/or bottom wall are at least partially inclined between the first and second side wall of the cage. In one embodiment, the top wall and/or bottom wall are uniformly inclined from the first and second side wall. In one specific embodiment, the second side wall is higher than the first side wall. In another specific embodiment, the angle of inclination of the top and/or bottom wall is about 0.5 to 15 degrees and preferably about 1 to 10 degrees and more preferably about 3 to 8 degrees. The inclination of the top and/or bottom wall of the cage facilitates in the ease of insertion into the vertebrae column and/or provides a better fit for the cage within the intervertebral disk space since the inclination better matches the anatomical shape of the space between the vertebrae of the spinal column.

In accordance with another aspect of the present invention, a pair of cages are used to support and/or fuse two vertebrae in the spinal column. In one embodiment, the cages are positioned in a side by side relation to form a rigid transverse strut between adjacent vertebrae.

It is an object of the present invention to provide an improved prosthetic implant for insertion between two vertebrae.

It is another object of the present invention is to provide a prosthetic implant which better emulates the space between the vertebrae.

Yet another object of the present invention to provide a prosthetic implant which includes one or more ridges to help secure the prosthetic implant in position between the vertebrae.

It is yet another object of the present invention to provide a prosthetic implant which is used in a side by side relation to form a rigid transverse strut between adjacent vertebrae.

It is still yet another object of the present invention to provide a prosthetic implant which provides improved spinal support fixation and methodology which provides stability between adjacent vertebrae and the shape will facilitate in securing the prosthetic implant between the vertebrae.

Another object of the present invention is to provide an apparatus which will aid in the positioning of the prosthetic implant between the vertebrae.

Still yet another object of the present invention is to provide a prosthetic implant which has one or more openings that can receive packing material to facilitate in the fusion of two adjacently positioned vertebrae.

A further object of the present invention is to provide a prosthetic implant which can be easily and efficiently positioned between two vertebrae and which reduces the failure rate of prosthetic implants between the vertebrae.

It is another object of the present invention to provide a prosthetic implant which includes one or more sloped surfaces to facilitate in the insertion of the prosthetic implant between the adjacently positioned vertebrae and to better match the shape of the prosthetic implant to the space between the adjacently positioned vertebrae.

It is still another object of the present invention to provide a prosthetic implant which includes surfaces that reduce pinching with the spinal cord and other body parts closely adjacent to the prosthetic implant.

It is another object of the present invention to provide a prosthetic implant that is made of a biologically compatible material.

It is another object of the present invention to provide a prosthetic implant that is made of and/or coated with a radiolucent material.

It is another object of the present invention to provide a prosthetic implant that is made of a material which closely approximates the elasticity of the vertebra.

These and other objects of the invention will become apparent to those skilled in the art upon reading and understanding the following detailed description of preferred embodiments taken together with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take physical form in certain parts and arrangement of parts, preferred embodiments of which will be described in detail and illustrated in the accompanying drawings which form a part hereof and wherein:

FIG. **1** is a top plan view of the prosthetic implant of the present invention;

FIG. **2** is a prospective view of the prosthetic implant of the present invention;

FIG. **3** is a side elevation view of the prosthetic implant of the present invention;

FIG. **3A** is an enlarged view of an alternate ridge configuration in the top wall of the prosthetic implant of FIG. **3**;

FIG. **4** is prospective view of another embodiment of the prosthetic implant of the present invention which illustrates the dual sloping of the top and bottom walls of the prosthetic implant;

FIG. **4A** is a rear end view of the prosthetic implant in FIG. **4**;

FIG. **5** is a side elevation view of a spinal column which includes the prosthetic implant of the present invention positioned between two adjacently positioned vertebrae; and

FIG. **6** is a posterior elevation view of a portion of FIG. **5** illustrating two adjacently positioned prosthetic implants positioned between two spinal vertebrae.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, wherein the showings are for the purpose of illustrating the preferred embodiment of the invention only and not for the purpose of limiting same, FIGS. **1–3** illustrate a prosthetic device or implant **10** which is designed to be inserted in an intervertebral disk space between two vertebrae of the spinal column. Prosthetic implant **10** is illustrated as being a cage-like structure **12** having a top wall **20**, a bottom wall **30**, a front end wall **40**, a back end wall **50**, a first side wall **60**, and a back side wall **70**. As best illustrated in FIGS. **1** and **2**, the top wall **20** includes a plurality of ridge structures **80** which are positioned along the longitudinal length of prosthetic implant **10**. As illustrated in FIG. **3**, ridge structures **80** are also included on bottom wall **30**. The ridge structures can be cut into the top and bottom walls and/or be formed by a molding process. The ridge structures are designed to bite into and/or readily form a rigid contact with the underside surface of the vertebrae so as to secure the prosthetic implant between the vertebrae and reduce the movement of the prosthetic implant of the vertebrae after the prosthetic implant has been properly positioned between the vertebrae.

Referring to FIGS. **1** and **2**, ridge structures **80** are shown to be spaced from the peripheral edge **22** of top wall **20**. This same spacing of the ridges also exists on the bottom wall. Top wall **20** is also shown to include an opening **100**. Many different ridge configurations can be used on the top and bottom walls of cage **10**. Two preferable configurations are illustrated in FIGS. **1** and **3A**. In FIG. **1**, the ridge structures are groove type ridges that are oriented along the lateral axis of cage **12**. The ridge structures have two sides that are similar in length. In one arrangement, the height of the ridge structure from valley to peak is about 0.01 to 0.05 inch, and the spacing between ridge peaks is about 0.01 to 0.12 inch. As can be appreciated, these dimensions of the ridge structures can be modified for use in a particular application.

Referring now to FIG. **3A**, an alternative configuration of the ridge structure is shown. Ridge structures **80** are generally diamond shaped structures wherein each ridge structure has four walls. The walls **82** of the diamond shaped ridge structure are generally the same size and shape. In one arrangement, the height of the ridge structure from valley to peak is about 0.01 to 0.05 inch, and the spacing between ridge peaks is about 0.01 to 0.12 inch. As can be appreciated, these dimensions of the ridge structures can be modified for use in a particular application.

The ridge structures can be oriented in the top and/or bottom wall to facilitate in the stacking or two or more prosthetic implants.

Referring to FIGS. **1** and **4**, the top and bottom wall of cage **12** includes an openings **100, 120**. Openings **100, 120** are illustrated as being semi-oval shaped; however, other opening shapes can be used. The size of the opening is selected so packing materials **300** can be inserted in the openings. In one desired arrangement, the size of openings **100, 120** are maximized to increase the volume of packing materials that can be inserted into the cage without adversely affecting the structural integrity of the cage. As illustrated in FIGS. **1** and **4**, openings **100** and **120** have a similar shape and size; however, other shapes and sizes of the openings can be used. The openings are shown to have a peripheral edge spaced at a generally uniform distance from the peripheral edge of the top and bottom wall. In one desired arrangement, the spacing of the peripheral edge of the opening from the peripheral edge of the top and bottom walls is about 0.05 to 0.25 inch; however, other spacings can be used based upon the material and size of the cage.

Referring now to FIGS. **1, 2** and **4**, cage **12** includes a cavity **130**. Cavity **130** is shown to be in communication with opening **100, 120** in the top and bottom walls of cage **12**. The cavity is designed to increase the amount of packing material that can be inserted in the cage. The packing material **300** includes, but is not limited to, medicine, tissue, cells, and the like. In one desired arrangement, the packing material is selected to facilitate in the growth of bone between the two vertebrae in which the prosthetic implant is inserted therebetween.

Referring now to FIG. **2**, the first side wall **60** has an arcuate or curvilinear shape along the longitudinal length of the wall. The arcuate shape of the first side wall is selected to more closely anatomically match the intervertebral disk space. Second side wall **70** is illustrated as having a substantially straight or planar face. When prosthetic implant **10** is positioned in the intervertebral disk space, second side wall **70** is positioned closely adjacent to the spinal cord and first side wall **60** is positioned adjacent the outer edge of the vertebrae. The curvilinear first side wall and the substantially planar or straight second side wall are designed to more closely match the intervertebral disk space and to increase the surface area of contact with the vertebrae to assist in reducing slippage and to increase the success rate of the fusion between two vertebrae. As can be appreciated, the

shape of the arcuate surface of first side wall **60** can be adjusted depending on the vertebrae in which the prosthetic implant is to be inserted therebetween. As also can be appreciated, second side wall **70** may also be shaped to include non-planar surfaces to further facilitate in the maximization of contact of the surfaces of the prosthetic implant to the underside surfaces of the vertebrae. In one desired embodiment, the planar second side wall has a length of about 0.5 to 1.2 inch and a height of about 0.2 to 0.8 inch. In another desired embodiment, the radius of curvature of the first side wall is about 0.3 to 0.9 inch and a height of about 0.1 to 0.75 inch. As can be appreciated, the size and configuration of the side wall can take on other dimensions and configurations depending on the use of the prosthetic implant.

Referring again to FIG. **2**, first side wall **60** and second side wall **70** include openings **140** which communicate with inner cavity **130**. As with openings **100** and **120** in the top and bottom walls, openings **140** are designed to receiving packing material **300** and to allow for blood flow between the packing material within the cavity **130** and the surrounding regions of the vertebrae. Openings **140** are illustrated as being diamond shaped; however, other shapes can be used. The side walls are also illustrated as each including two openings **140**; however, more or less openings can be included in the side walls. In one desire embodiment, oval or diamond shaped openings are used in the side walls to maximize the opening size without adversely affecting the structural integrity of the cage.

Referring again to FIG. **2**, the side walls include an instrument opening **150** which is designed to receive an instrument to enable the prosthetic device to be inserted in the intervertebral disk space in number of different approaches. In one desired embodiment, the prosthetic implant includes a plurality of instrument opening **150** to enable the prosthetic implant to be inserted in the intervertebral disk space from an anterior, posterior, lateral, and/or lateralscopic approach to the vertebrae. In another desired embodiment, the instrument opening **150** is a threaded opening which receives a threaded instrument. The threaded opening allows an instrument to be simply secured to and/or removed from the prosthetic implant **10**. The instrument opening **150** can also be used to secure pedicle screws to the prosthetic implant so as to facilitate attachment to a rod or plate stabilization system to the prosthetic implant.

Referring now to FIGS. **2** and **4**, front and back end walls **40**, **50** include an instrument opening **160**. The configuration and function of instrument opening **160** is the same as instrument opening **150** in the first and second walls of cage **12**.

Referring now to FIG. **2**, the peripheral edges of the walls of the cage are rounded off or contoured. The rounded off edges **200** are designed to minimize or eliminate sharp edges on the cage to reduce and/or eliminate pinching of the nerves, and to facilitate in the positioning of the cage in the intervertebral disk space.

Referring now to FIG. **3**, the top and bottom walls of the cage are inclined. Top wall **20** and bottom wall **30** are shown to slope downwardly from back end wall **50** to front end wall **40**. The angle of incline is shown to be generally uniform throughout the longitudinal length of the prosthetic implant. The degree of inclination of both the top wall and bottom wall of the prosthetic implant is substantially the same. Due to the sloping surfaces of the top and bottom wall, the back end wall **50** is shown to have a higher height than front wall **40**. In one desired embodiment, the height of the back end wall is about 0.2 to 0.8 inch, the height of the front side wall is about 0.1 to 0.75 inch, and the angle of slope of the top and bottom wall from the back to front end wall is about 0.5 to 20 degrees.

Referring now to FIGS. **3**, **4** and **4A**, the top and bottom walls of cage **12** are inclined from the second side wall to the first side wall. In one desired embodiment, the degree of inclination of the top and bottom wall from the second side wall to the first side wall is substantially uniform. Due to the incline of the top and bottom wall, the second side wall has a higher height than the first side wall. In another desired embodiment, the angle of slope of the top and bottom wall from the back to front end wall is about 0.5 to 20 degrees.

Referring now to FIGS. **5** and **6**, the lower portion of the human vertebrae column **210** is illustrated. FIG. **5** illustrates five lower vertebrae of the spinal column. Vertebrae **220** and **230** are separated by and supported on the prosthetic implant **10** of the present invention. The remaining vertebrae are illustrated as being supported on and separately by intervertebral disk **250** which maintains a space **260** between the adjoining vertebrae. The damaged portions of intervertebral disk **250** have been removed from between vertebrae **220** and **230** prior to prosthetic implant **10** being inserted therebetween. As shown in FIG. **6**, two prosthetic implants **10** are positioned side by side between vertebrae **220** and **230**.

As an overview of one embodiment of the invention, the prosthetic implant is a solid structure of a cage having one or more cavities. The implant is to be inserted into the vertebral column during surgery to provide load bearing support for the vertebrae in the vertebral column. The implant is shaped to provide a slope laterally so that the medium aspect closest to the spinal column is higher than the lateral aspect. The implant has one or more openings in the cage to allow for packing materials not rejected by the human body. These packing materials include, but are not limited to, autologous bone, donated human bone material, other mammalian materials, and/or other natural or artificial materials. The cage is sloped from the anterior to the posterior. The cage has rounded edges to reduce spinal pinching. The top and bottom walls of the cage include ridges or grooves that are carved into the top and bottom walls to facilitate in the fixation and anchoring of the cage between two vertebrae. The ridges can have several configurations, one being a cross hatched or teeth design which form diamond bumps or pyramids. The cage has one or more arcuate or curvilinear sides that forms an ovoid shaped cage or a double domed disk configuration.

In the most common applications, two prosthetic implants will be utilized and inserted in the intervertebral disk space, one on each side of the lateral sides of the spinal column. The prosthetic devices will replace a damaged or injured disk that is partially or wholly removed during a surgical procedure. During the surgical procedure, the implants will be inserted and fixed in a location to avoid intrusion into the spinal cord area while at the same time avoiding extending outside the vertebral column. This placement of the prosthetic implants is optimized by utilizing the prosthetic implant of the present invention.

Some advantages and improvements of the prosthetic implant over prior art implants are:

- The comers of the implant are rounded.
- The top wall of the implant slopes from one side wall to another side wall.
- The bottom wall of the implant slopes from one side wall to another side wall.
- The top wall of the implant slopes from one end wall to another end wall.

The bottom wall of the implant slopes from one end wall to another end wall.

The implant includes larger and/or more openings to facilitate in the packing of the implant with bone and/or bone growth promoters.

The top and/or bottom surfaces of the implant include ridged surfaces having a diamond shaped design for better bone anchoring.

The walls of the implant include one or more threaded holes to enable the implant to be inserted from the anterior, posterior, lateral, or laproscopic approach during surgery.

The implant is designed to receive interference screws and/or stints used to inhibit the migration of the implant within the intervertebral disk space.

The implant can be made of a variety of materials such as chopped carbon fiber/polymer, other polymers, various metals, memory metals, ceramics, bone, bioresorbables, and/or composites.

The implant can be made of a memory metal that can be expanded after being inserted in the intervertebral disk space. The cage can be designed to be expanded "in vivo."

The implant can be used with a modular component that can be attached and assembled between two implants to create a construct (ALIF type) cage.

The implant can be stacked upon one another to form a corpectomy cage having various shapes and sizes.

The implant is designed to accept insertion of machine-threaded pedicle screws so as to facilitate attachment to a rod or plate stabilization system.

The invention has been described with reference to the preferred embodiments. These and other modifications of the preferred embodiments as well as other embodiments of the invention will be obvious from the disclosure herein, whereby the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation. It is intended to include all such modifications and alterations in so far as they come within the scope of the appended claims.

I claim:

1. A prosthetic implant to form a rigid structure between adjoining vertebrae in a spinal column comprising a cage defined by top, bottom, front end, back end, first side and second side walls, said first and second side walls extending substantially along a longitudinal axis of said cage, said front and back end walls having a width less than the length of said first side and said second side walls, said top wall and said bottom wall positionable between and engageable with a surface of an adjacent vertebrae, said first side wall having an arcuate surface, said second side wall being a substantially planar surface, said top wall being inclined downwardly from said back end wall to said front end wall such that at least a portion of said back end wall has a height greater than a height of at least a portion of said front end wall.

2. The prosthetic implant as defined in claim 1, wherein said top wall includes at least one ridge to engage a surface of an adjacent vertebrae.

3. The prosthetic implant as defined in claim 1, wherein said bottom wall includes at least one ridge to engage a surface of an adjacent vertebrae.

4. The prosthetic implant as defined in claim 2, wherein said top wall includes a plurality of ridges.

5. The prosthetic implant as defined in claim 2, wherein at least one of said ridge includes a plurality of teeth.

6. The prosthetic implant as defined in claim 2, wherein said ridge being spaced from a peripheral edge of said first or second side wall.

7. The prosthetic implant as defined in claim 1, wherein said top wall including an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

8. The prosthetic implant as defined in claim 1, wherein said bottom wall including an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

9. The prosthetic implant as defined in claim 1, wherein said top wall having a peripheral edge, at least a portion of said peripheral edge being contoured so as not to be sharp.

10. The prosthetic implant as defined in claim 1, wherein said bottom wall having a peripheral edge, at least a portion of said peripheral edge being contoured so as not to be sharp.

11. The prosthetic implant as defined in claim 1, wherein said top wall being inclined from said second side wall to said first side wall.

12. The prosthetic implant as defined in claim 1, wherein said bottom wall being inclined from said second side wall to said first side wall.

13. The prosthetic implant as defined in claim 1, wherein said incline of said top wall being having a substantially constant slope.

14. The prosthetic implant as defined in claim 1, wherein said bottom wall being inclined from said back end wall to said front end wall.

15. The prosthetic implant as defined in claim 1, wherein said first side wall including an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

16. The prosthetic implant as defined in claim 1, wherein said second side wall including an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, blood, stem cells and combinations thereof.

17. The prosthetic implant as defined in claim 1, wherein at least one of said front end wall, said back end wall, said first side wall and said second side wall including an opening, said opening adapted to receive an instrument to guide said prosthetic implant between adjoining vertebrae in a spinal column, to receive an implant to secure said cage in position relative to said vertebrae, and combinations thereof.

18. The prosthetic implant as defined in claim 1, wherein said first side wall being a substantially uniform arcuate surface.

19. A prosthetic implant to form a rigid structure between adjoining vertebrae in a spinal column comprising a cage defined by top, bottom, front end, back end, first side and second side walls, said first and second side wall extending substantially along a longitudinal axis of said cage, said front and back end walls having a width that is less than the length of said first side and said second side walls, said top wall and said bottom wall positionable between and engageable with a surface of an adjacent vertebrae, at least one of said top and bottom walls being inclined downwardly from said second side wall to said first side wall such that at least a portion of said second side wall has a height greater than a height of at least a portion of said first side wall.

20. The prosthetic implant as defined in claim 19, wherein both said top and bottom walls being inclined from said second side wall to said first side wall.

21. The prosthetic implant as defined in claim 19, wherein said second side wall being higher that said first side wall.

22. The prosthetic implant as defined in claim 19, wherein said top and bottom walls include a plurality of ridges to engage a surface of an adjacent vertebrae.

23. The prosthetic implant as defined in claim 22, wherein said ridges include a plurality of teeth.

24. The prosthetic implant as defined in claim 19, wherein said ridges are spaced from a peripheral edge of said first and second side wall.

25. The prosthetic implant as defined in claim 19, wherein said top and bottom walls include an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

26. The prosthetic implant as defined in claim 19, wherein said top, bottom, front end, back end, first side and second side walls each having a peripheral edge, at least a portion of said peripheral edges of each of said walls being contoured so as not to be sharp.

27. The prosthetic implant as defined in claim 19, wherein said top and bottom walls are inclined from said back end wall to said front end wall.

28. The prosthetic implant as defined in claim 19, wherein said back side wall being higher than said front side wall.

29. The prosthetic implant as defined in claim 19, wherein at least one of said front end wall, said back end wall, said first side wall and said second side wall including an opening, said opening adapted to receive an instrument to guide said prosthetic implant between adjoining vertebrae in a spinal column, to receive an implant to secure said cage in position relative to said vertebrae, and combinations thereof.

30. The prosthetic implant as defined in claim 29, including a cavity within said cage, said cavity in communication with said at least one of said opening in at least one of said front end, said back end, said first side and said second side walls, said cavity adapted to receive packing material that includes a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

31. The prosthetic implant as defined in claim 19, wherein said front side wall having a substantially uniform arcuate surface.

32. A prosthetic implant to form a rigid structure between adjoining vertebrae in a spinal column comprising a cage defined by top, bottom, front end, back end, first side and second side walls, said first and second side walls extending substantially along a longitudinal axis of said cage, said front and back end walls having a width less than the length of said first side and said second side walls, said top wall and said bottom wall positionable between and engageable with a surface of an adjacent vertebrae, said first side wall having an arcuate surface, at least one of said top and bottom walls being inclined downwardly from said back end wall to said front end wall such that at least a portion of said back end wall has a height greater than a height of at least a portion of said front end wall, at least one of said top and bottom walls being inclined downwardly from said second side wall to said first side wall such that at least a portion of said second side wall has a height greater than a height of at least a portion of said first side wall.

33. The prosthetic implant as defined in claim 32, wherein said top wall includes a plurality of ridges to engage a surface of an adjacent vertebrae, at least one of said ridge includes a plurality of teeth.

34. The prosthetic implant as defined in claim 32, wherein said bottom wall includes a plurality of ridges to engage a surface of an adjacent vertebrae, at least one of said ridge includes a plurality of teeth.

35. The prosthetic implant as defined in claim 33, wherein said top wall includes a plurality of ridges to engage a surface of an adjacent vertebrae, at least one of said ridge includes a plurality of teeth.

36. The prosthetic implant as defined in claim 35, wherein said plurality of ridges are spaced from a peripheral edge of said first and second side wall.

37. The prosthetic implant as defined in claim 32, wherein said top wall and said bottom being inclined from said second side wall to said first side wall.

38. The prosthetic implant as defined in claim 32, wherein incline of said top wall from said second side wall to said first side wall having a substantially constant slope.

39. The prosthetic implant as defined in claim 32, in incline of said bottom wall from said second side wall to said first side wall having a substantially constant slope.

40. The prosthetic implant as defined in claim 37, wherein incline of said top wall and said bottom wall from said second side wall to said first side wall having a substantially constant slope.

41. The prosthetic implant as defined in claim 32, wherein said top wall and said bottom being inclined from said back end wall to said front end wall.

42. The prosthetic implant as defined in claim 40, wherein said top wall and said bottom being inclined from said back end wall to said front end wall.

43. The prosthetic implant as defined in claim 32, wherein incline of said top wall from said back end wall to said front end wall having a substantially constant slope.

44. The prosthetic implant as defined in claim 32, wherein incline of said bottom wall from said back end wall to said front end wall having a substantially constant slope.

45. The prosthetic implant as defined in claim 41, wherein incline of said top wall and said bottom wall from said back end wall to said front end wall having a substantially constant slope.

46. The prosthetic implant as defined in claim 42, wherein incline of said top wall and said bottom wall from said back end wall to said front end wall having a substantially constant slope.

47. The prosthetic implant as defined in claim 32, wherein said top wall including an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

48. The prosthetic implant as defined in claim 32, wherein said bottom wall including an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

49. The prosthetic implant as defined in claim 32, wherein said first side wall including an opening to receive packing material, said packing material including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and combinations thereof.

50. The prosthetic implant as defined in claim 32, wherein said second side wall including an opening to receive packing material, said packing material including a material

selected from the group consisting of medicine, human tissue, animal tissue, blood, stem cells and combinations thereof.

51. The prosthetic implant as defined in claim **32**, wherein said top, bottom, front end, back end, first side and second side walls each having a peripheral edge, at least a portion of said peripheral edges of each of said walls being contoured so as not to be sharp.

52. The prosthetic implant as defined in claim **32**, wherein at least one of said front end wall, said back end wall, said first side wall and said second side wall including an opening, said opening adapted to receive an instrument to guide said prosthetic implant between adjoining vertebrae in a spinal column, to receive an implant to secure said cage in position relative to said vertebrae, and combinations thereof.

53. The prosthetic implant as defined in claim **32**, wherein said first side wall being a substantially uniform arcuate surface.

54. The prosthetic implant as defined in claim **32**, wherein said second side wall being a substantially planar surface.

55. The prosthetic implant as defined in claim **53**, wherein said second side wall being a substantially planar surface.

56. The prosthetic implant as defined in claim **46**, wherein said first side wall being a substantially uniform arcuate surface.

57. The prosthetic implant as defined in claim **56**, wherein said second side wall being a substantially planar surface.

58. The prosthetic implant as defined in claim **32**, wherein said top, bottom, front end, back end, first side and second side walls each having a peripheral edge, at least a portion of said peripheral edges of each of said walls being contoured so as not to be sharp.

59. The prosthetic implant as defined in claim **58**, wherein said top wall includes a plurality of ridges to engage a surface of an adjacent vertebrae, at least one of said ridge includes a plurality of teeth.

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